

IN THE CHANCERY COURT OF DAVIDSON COUNTY, TENNESSEE

STEPHEN MICHAEL WEST,
BILLY RAY IRICK,
NICHOLAS TODD SUTTON,
DAVID EARL MILLER, and
OLEN EDWARD HUTCHISON,

Plaintiffs,

v.

DERRICK D. SCHOFIELD, in his official
capacity as Tennessee's Commissioner of
Correction,

WAYNE CARPENTER, in his official
capacity as Warden of Riverbend Maximum
Security Institution,

TONY MAYS, in his official
capacity as Deputy Warden of Riverbend Maximum
Security Institution,

JASON WOODALL, in his official capacity
as Deputy Commissioner of Operations,

TONY PARKER, in his official capacity
as Assistant Commissioner of Prisons,

JOHN DOE PHYSICIANS 1-100,

JOHN DOE PHARMACISTS 1-100,

JOHN DOE MEDICAL EXAMINERS 1-100,

JOHN DOE MEDICAL PERSONNEL 1-100,

JOHN DOE EXECUTIONERS 1-100.

Defendants.

No. _____

Death Penalty Case

COMPLAINT FOR DECLARATORY JUDGMENT

TABLE OF CONTENTS

INTRODUCTION	{2}
JURISDICTION AND VENUE	{4}
PARTIES	{5}
DEFENDANTS' EXECUTION PROTOCOL	{11}

COUNT I

Violation of the Eighth and Fourteenth Amendments of the United States constitution and Tennessee constitution Article 1, § 16 through adherence to the Lethal Injection Protocol which creates a substantial risk of unnecessary pain when carried out exactly in the manner prescribed	{18}
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COUNT II

Violation of the Eighth and Fourteenth Amendments to the United States Constitution and Tennessee Constitution Article 1, § 16 through adherence to the Lethal Injection Protocol which will require the use of compounded pentobarbital	{22}
--	------

A. There is a substantial risk that Defendants' will use APIs from non-FDA-approved sources in the compounding of pentobarbital for use in the Lethal Injection Protocol thereby producing pentobarbital that is non-sterile, impure, adulterated, sub-potent, and/or counterfeit	{24}
B. There is a substantial risk that Defendants will use pentobarbital compounded by a pharmacy producing pentobarbital that is non-sterile, impure, adulterated, and/or sub-potent	{27}
C. Defendants' use of pentobarbital of a different concentration than required in the Lethal Injection Protocol creates a substantial risk of unnecessary pain and suffering	{30}
D. Defendants' use of non-sterile, impure, adulterated, sub-potent, and/or counterfeit pentobarbital in the Lethal Injection Protocol creates a substantial risk of unnecessary pain and suffering	{31}
i. Bacterial and fungal contamination	{31}
ii. Contamination by particulate matter	{33}
iii. Sub-potency	{33}

COUNT III

Violation of the Eighth and Fourteenth Amendment and Tennessee Constitution Article 1, § 16 through adherence to the Lethal Injection Protocol which fails to provide adequate qualifications and training of personnel to minimize the known risks involved in execution by lethal injection {35}

COUNT VI

Violation of the Eighth and Fourteenth Amendments to the United States Constitution and Tennessee Constitution Article 1, § 16 through adherence to the Lethal Injection Protocol which fails to require and include, and fails to comport with, those accepted medical practices necessary to minimize the known risks involved in execution by lethal injection {43}

COUNT VII

The Lethal Injection Protocol violates federal and state drug laws and the United States and Tennessee Constitutions {51}

- A. In Violation of the Supremacy Clause of the United States Constitution (Article VI § 2), Defendants' Lethal Injection Protocol providing for the procurement and use of pentobarbital and/or compounded pentobarbital is facially void and unlawful {59}
- B. Defendants' Lethal Injection Protocol and use and attempted use upon Plaintiffs of pentobarbital and/or compounded pentobarbital is unlawful and illegal and violates the Eighth and Fourteenth Amendments to the United States Constitution {60}
- C. As applied to Plaintiffs, Defendants' Lethal Injection Protocol and use and attempted use upon Plaintiffs of pentobarbital and/or compounded pentobarbital is unlawful and illegal and violates the Supremacy Clause of the United States Constitution (Article VI § 2) {61}
- D. Facially and as applied to Plaintiffs, Defendants' Lethal Injection Protocol and its use and attempted use upon plaintiffs is void and unlawful and violates Article I § 8 of the Tennessee Constitution {62}
- E. Facially and as applied to Plaintiffs, Defendants' Lethal Injection Protocol and its use and attempted use upon plaintiffs violates state law and Article I, §§ 8 and 16 of the Tennessee Constitution {63}
- F. Facially and as applied to Plaintiffs, Defendants' Lethal Injection Protocol and its use and attempted use upon Plaintiffs is void for public policy {64}
- G. Defendants are illegally and unlawfully engaged in a civil conspiracy to unlawfully harm and to execute Plaintiffs {65}

COUNT VIII

Tennessee's secrecy statute, Tenn. Code Ann. § 10-7-504(h)(1), violates Plaintiffs' federal and state constitutional rights and 42 U.S.C. § 1983 {66}

A. Tennessee Code Annotated § 10-7-504(h)(1) denies Plaintiffs access to the courts .. {69}

B. Tennessee Code Annotated § 10-7-504(h)(1) denies Plaintiffs Due Process {71}

C. Tennessee Code Annotated § 10-7-504(h)(1) violates the Supremacy Clause {72}

D. Tennessee Code Annotated § 10-7-504(h)(1) violates separation of powers
as set forth in Article II, § 2 of the Tennessee Constitution {74}

PRAYER FOR RELIEF {75}

CERTIFICATE OF SERVICE {77}

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COMPLAINT FOR DECLARATORY JUDGMENT

Come the Plaintiffs, Stephen Michael West, Billy Ray Irick, Nicholas Todd Sutton, David Earl Miller, and Olen Edward Hutchison, and hereby file this Complaint against the above-named defendants, showing the Court as follows:

INTRODUCTION

1. Plaintiff, Stephen Michael West, is a condemned inmate under a sentence of death rendered in Union County, Tennessee. He is currently incarcerated at Riverbend Maximum Security Institution in Nashville, Tennessee ("RMSI"). Plaintiff West is facing an imminent execution date. On October 3, 2013, the State moved the Tennessee Supreme Court to schedule such a date.

2. Plaintiff, Billy Ray Irick, is a condemned inmate under a sentence of death rendered in Knox County, Tennessee. He is currently incarcerated at RMSI. Plaintiff Irick is confronted with an execution date of January 15, 2014.

3. Plaintiff, Nicholas Todd Sutton, is a condemned inmate under a sentence of death rendered in Morgan County, Tennessee. He is currently incarcerated at RMSI. Plaintiff Sutton is facing an imminent execution date. On October 3, 2013, the State moved the Tennessee Supreme Court to schedule such a date.

4. Plaintiff, David Earl Miller, is a condemned inmate under a sentence of death rendered in Knox County, Tennessee. He is currently incarcerated at RMSI. Plaintiff Miller is facing an imminent execution date. On October 3, 2013, the State moved the Tennessee Supreme Court to schedule such a date.

5. Plaintiff, Olen Edward Hutchison, is a condemned inmate under a sentence of death rendered in Knox County, Tennessee. He is currently incarcerated at RMSI. Plaintiff

Hutchison is facing an imminent execution date. On October 3, 2013, the State moved the Tennessee Supreme Court to schedule such a date.

6. Tennessee Code Annotated § 40-23-114 provides:

§ 40-23-114. Capital punishment; electrocution; lethal injection

(a) For any person who commits an offense for which the person is sentenced to the punishment of death, the method for carrying out this sentence shall be by lethal injection.

(b) Any person who commits an offense prior to January 1, 1999, for which the person is sentenced to the punishment of death may elect to be executed by electrocution by signing a written waiver waiving the right to be executed by lethal injection.

(c) The department of correction is authorized to promulgate necessary rules and regulations to facilitate the implementation of this section.

(d) If lethal injection or electrocution is held to be unconstitutional by the Tennessee supreme court under the Constitution of Tennessee, or held to be unconstitutional by the United States supreme court under the United States Constitution, or if the United States supreme court declines to review any judgment holding lethal injection or electrocution to be unconstitutional under the United States Constitution made by the Tennessee supreme court or the United States court of appeals that has jurisdiction over Tennessee, or if the Tennessee supreme court declines to review any judgment by the Tennessee court of criminal appeals holding lethal injection or electrocution to be unconstitutional under the United States or Tennessee constitutions, all persons sentenced to death for a capital crime shall be executed by any constitutional method of execution. No sentence of death shall be reduced as a result of a determination that a method of execution is declared unconstitutional under the Constitution of Tennessee or the Constitution of the United States. In any case in which an execution method is declared unconstitutional, the death sentence shall remain in force until the sentence can be lawfully executed by any valid method of execution.

7. Plaintiffs have not elected a method of execution. Accordingly, under Tennessee Code Annotated § 40-23-114(a) and (b), his sentence will be carried out by lethal injection.

8. On September 27, 2013, the Tennessee Department of Correction issued its Execution Procedures for Lethal Injection (hereinafter "Lethal Injection Protocol"). The

September 27 protocol constitutes a substantial change from the previous protocol. The protocol provides that Plaintiffs' execution shall be carried out by the injection of a single drug, pentobarbital. A copy of the Lethal Injection Protocol is attached hereto as Plaintiffs' Exhibit A.

9. On October 3, 2013, the Tennessee Attorney General sought execution dates for the Plaintiffs and five other condemned Tennessee inmates.

JURISDICTION AND VENUE

10. Venue is proper in this Court because Plaintiffs are incarcerated at Riverbend Maximum Security Institution, in this county; the Defendants intend to procure and inject Plaintiffs with pentobarbital and thereby execute them in this county. Accordingly, the events giving rise to this Complaint have occurred and will occur in this county.

11. This action arises under Tennessee Constitution Article 1, §§ 2, 8, 16, 17, and Article VI, § 2 of the United States Constitution, and, the First, Eighth, and Fourteenth Amendments to the United States Constitution, 42 U.S.C. § 1983, and state and federal law as set forth in Claim VII.

12. The Eighth Amendment prohibits cruel and unusual punishment, for example, executions which "involve the unnecessary and wanton infliction of pain," *Gregg v. Georgia*, 428 U.S. 153, 173 (1976), or which "involve torture or a lingering death." *In re Kemmler*, 136 U.S. 436, 447 (1890) (citing *Wilkinson v. Utah*, 99 U.S. 130, 135 (1878)); *Gregg*, 428 U.S. at 170. Unnecessary and wanton infliction of pain is defined as the gratuitous infliction of suffering. It is not limited to physical pain, but includes psychological torture as well. *Calhoun v. DeTella*, 319 F.3d 936, 939 (7th Cir. 2003).

13. Subjecting individuals to a future risk of harm can qualify as cruel and unusual punishment. *Baze v. Rees*, 553 U.S. 35, 49 (2008). To prevail on an Eighth Amendment claim there must be a “substantial risk of serious harm,” or an “objectively intolerable risk of harm.” *Baze*, 553 U.S. at 50.

14. This Court has jurisdiction pursuant to Tenn. Code Ann. §§ 29-14-103, 29-14-113.

15. As to exhaustion of administrative remedies, on October 1, 2013, shortly after Tennessee adopted the Lethal Injection Protocol, Plaintiffs filed a grievance, objecting to the use of the Lethal injection Protocol for their executions. The grievances were denied and Plaintiffs timely appealed.

PARTIES

16. Plaintiff Stephen Michael West is a United States citizen. He is a death-sentenced prisoner residing in Davidson County at RMSI and in the custody of the Tennessee Department of Correction.

17. Plaintiff Billy Ray Irick is a United States citizen. He is a death-sentenced prisoner residing in Davison County at RMSI and in the custody of the Tennessee Department of Correction.

18. Plaintiff Nicholas Todd Sutton is a United States citizen. He is a death-sentenced prisoner residing in Davison County at RMSI and in the custody of the Tennessee Department of Correction.

19. Plaintiff David Earl Miller is a United States citizen. He is a death-sentenced prisoner residing in Davison County at RMSI and in the custody of the Tennessee Department of Correction.

20. Plaintiff Olen Edward Hutchison is a United States citizen. He is a death-sentenced prisoner residing in Davison County at RMSI and in the custody of the Tennessee Department of Correction.

21. Defendant Derrick Schofield is the Commissioner of the Tennessee Department of Correction. Plaintiffs sue Commissioner Schofield in his official capacity. Defendant Schofield will oversee the administration of Plaintiffs' executions at RMSI (Plaintiffs' Exhibit A p.5). Defendant Schofield is a state actor acting under color of state law, and his actions in seeking to execute and/or executing Plaintiffs under the Lethal Injection Protocol as described *infra* violate Plaintiffs' constitutional rights, as described *infra*.

22. Defendant Wayne Carpenter is the Warden of RMSI, located in Nashville, Tennessee, in this county and where Plaintiffs' executions will occur. Plaintiffs sue Warden Carpenter in his official capacity. Defendant Carpenter is directly in charge of executing Plaintiffs at RMSI. His role in Plaintiffs' execution is described in the Lethal Injection Protocol (Plaintiffs' Exhibit A pp.12-13, 36-37, 43). Defendant Carpenter is a state actor acting under color of state law, and his actions in seeking to execute or executing Plaintiffs under the Lethal Injection Protocol as described *infra* violate their constitutional rights, as described *infra*.

23. Defendant Tony Mays is the Deputy Warden of RMSI, located in Nashville, Tennessee, in this county and where Plaintiffs' executions will occur. Plaintiffs sue Deputy

Warden Mays in his official capacity. Defendant Mays assists the Warden in performing execution procedures and substitutes for the Warden if he is unable to perform his duties. His role in Plaintiffs' executions is described in the Lethal Injection Protocol (Plaintiffs' Exhibit A p.14, 50-51). Defendant Mays is a state actor acting under color of state law, and his actions in seeking to execute or executing Plaintiffs under the Lethal Injection Protocol as described *infra* violate their constitutional rights, as described *infra*.

24. Defendant Jason Woodall is the Deputy Commissioner of Operations. Plaintiffs sue Deputy Commissioner Woodall in his official capacity. Defendant Woodall is a state actor acting under color of state law. Defendant Woodall will participate in Plaintiffs' executions, as described in the Current Protocol (Plaintiffs' Exhibit A pp.27, 66). Defendant Woodall's actions in seeking to execute or executing Plaintiffs under the Current Protocol as described *infra* violate their constitutional rights, as described *infra*.

25. Defendant Tony Parker is the Assistant Commissioner of Prisons. Plaintiffs sue Deputy Commissioner Parker in his official capacity. Defendant Parker is a state actor acting under color of state law. Defendant Parker will work directly with Defendant Schofield in overseeing Plaintiffs' executions and performing assigned duties (Plaintiffs' Exhibit A p.28). Defendant Parker's actions in seeking to execute or executing Plaintiffs under the Lethal Injection Protocol as described *infra* violate their constitutional rights, as described *infra*.

26. Defendants John Doe Physicians 1-100 are any and all medical doctors involved in the prescription, procurement and/or administration of pentobarbital for use upon Plaintiffs without the purpose to heal and without a legitimate medical reason, but to cause Plaintiffs'

deaths. In such capacity, they are state actors acting under color of state law, and their actions in seeking to execute or executing Plaintiffs under the Lethal Injection Protocol as described *infra* violate federal law and/or Plaintiffs' constitutional rights, as described *infra*. They are sued in their official capacity as state actors. Procurement and dispensing of pentobarbital is described in the Lethal Injection Protocol (Plaintiffs' Exhibit A p.36). Upon information and belief, pentobarbital must be prescribed by Defendants John Doe Physicians 1-100 and must be prescribed by a practitioner for a legitimate medical purpose acting in the usual course of his profession and possessing a registration under the Controlled Substances Act.

27. Defendant John Doe Physician 1 will perform a "cut-down procedure" in a manner within his unlimited discretion in the event a catheter cannot be successfully inserted by an EMT (Plaintiffs' Exhibit A p.41). Defendant John Doe Physician 1, however, also has unlimited discretion to use "a different method to find an IV site" instead of performing a "cut-down procedure." (Plaintiffs' Exhibit A p.67). Defendant John Doe Physician 1 will participate in Plaintiffs' executions as described in the Lethal Injection Protocol (Plaintiffs' Exhibit A pp.20, 41, 63, 65, 67). Defendant John Doe Physician 1 is a state actor acting under color of state law, and his/her actions in seeking to execute or executing Plaintiffs under the Lethal Injection Protocol as described *infra* violate federal law and/or Plaintiffs' constitutional rights, as described *infra*.

28. Defendants John Doe Pharmacists 1-100 are any and all persons involved in procuring, prescribing, dispensing, and/or compounding pentobarbital for use upon Plaintiffs without the purpose to heal and without a legitimate medical reason, but to cause Plaintiffs' deaths. Procurement and dispensing of pentobarbital is described in the Lethal Injection Protocol

(Plaintiffs' Exhibit A p.36). Such Defendants are state actors acting under color of state law, and their actions in seeking to execute or executing Plaintiffs under the Lethal Injection Protocol as described *infra* violate federal law and/or Plaintiffs' constitutional rights, as described *infra*. They are sued in their official capacity as state actors.

29. Defendants John Doe Medical Examiners 1-100 are any and all medical personnel involved in the transportation of Plaintiffs, and/or Plaintiffs' bodies to the State Medical Examiner, and/or the "examination and release" (Plaintiffs' Exhibit A p.66) of Plaintiffs and/or Plaintiffs' bodies after Plaintiffs are pronounced "deceased" by Physician 1 (Plaintiffs' Exhibit A p.65). Such Defendants may include, but are not limited to, Medical Examiner staff and the Medical Examiner who will participate in Plaintiffs' executions as described in the Lethal Injection Protocol (Plaintiffs' Exhibit A pp.65-66). Such Defendants are state actors acting under color of state law, and their actions in seeking to execute or executing Plaintiffs under the Lethal Injection Protocol as described *infra* violate Plaintiffs' constitutional rights, as described *infra*. They are sued in their official capacity as state actors.

30. Defendants John Doe Medical Personnel 1-100 are any and all medical personnel involved in using, preparing, or otherwise handling Plaintiffs or pentobarbital in any attempt to administer pentobarbital upon Plaintiffs without the purpose to heal and without a legitimate medical reason, but to cause Plaintiffs' deaths. Such Defendants may include, but are not limited to, EMTs who will participate in Plaintiffs' execution as described in the Lethal Injection Protocol (Plaintiffs' Exhibit A pp.32, 40-44, 63-66). Such Defendants are state actors acting under color of state law, and their actions in seeking to execute or executing Plaintiffs under the

Lethal Injection Protocol as described *infra* violate Plaintiffs' constitutional rights, as described *infra*. They are sued in their official capacity as state actors.

31. Defendants John Doe Executioners 1-100 are any and all other persons involved in using, preparing, or otherwise handling Plaintiffs or pentobarbital in any attempt to administer pentobarbital upon Plaintiffs. Such Defendants are state actors acting under color of state law, and their actions in seeking to execute or executing Plaintiffs under the Lethal Injection Protocol as described *infra* violate Plaintiffs' constitutional rights, as described *infra*. They are sued in their official capacity as state actors.

32. The State of Tennessee, through Defendants, seeks to execute Plaintiffs by lethal injection following the Lethal Injection Protocol as set forth in Plaintiffs' Exhibit A and as described *infra*. The default method of execution prescribed by Tennessee law is lethal injection. Tenn. Code Ann. § 40-23-114.

33. There are numerous alternate methods by which Defendants can execute Plaintiffs in a manner that reduces the substantial risk of inflicting unnecessary and serious pain alleged herein. Such methods are known to one or more Defendants. To the extent that Defendants claim that any such method is either not "feasible" or is not "readily implemented," it is because either: (a) Defendants' have prioritized considerations not protected by the constitutions of the State of Tennessee and/or the United States above the protections afforded Plaintiffs by Tennessee Constitution Article 1, § 16 and the Eighth and Fourteenth Amendments to the United States Constitution; or, (b) Defendants' carrying out of the executions of the Plaintiffs violates the evolving standards of decency by which the parties to the adoption of the Eighth Amendment

to the Constitution of the United States originally intended the definition of term “cruel and unusual punishment” to be determined.

34. To the extent relevant, each allegation made in this Complaint, regardless of where it appears within said Complaint, is made as to all causes of action.

DEFENDANTS’ EXECUTION PROTOCOL¹

35. The Lethal Injection Protocol (Plaintiffs’ Exhibit A) will be used for Plaintiffs’ executions.

36. Tennessee’s Lethal Injection Protocol consists of administering sequential injections of pentobarbital (Plaintiffs’ Exhibit A p.35).

Execution Procedures

37. Under the Lethal Injection Protocol, a physician’s order will be written by one or more of the Defendant(s) John Doe(s) Physician(s) asking for Defendant(s) John Doe(s) Pharmacist(s) for pentobarbital which Defendants would intend to administer to Plaintiffs to cause their deaths (Plaintiffs’ Exhibit A p.36). It is unclear that such “physician’s order” is actually written by a practitioner who may prescribe medicine and who possesses a registration under the Controlled Substances Act. It is clear, however, that such a prescription is not issued for a legitimate medical purpose.

38. It is unclear that Defendants who distribute and/or dispense pentobarbital for use in Plaintiffs’ executions possess a registration under the Controlled Substances Act.

¹When “he” is used as a pronoun in place of the name of an as yet to be determined Defendant, it is gender neutral and may refer to either a male or female defendant.

39. The Lethal Injection Protocol specifies that the Plaintiffs are to be injected with 100 ml of the barbiturate, pentobarbital, in a 50 mg/ml solution, for a total of 5 grams of pentobarbital (Plaintiffs' Exhibit A p.35).

40. The Lethal Injection Protocol provides instructions for the set-up and administration of 100 ml of pentobarbital solution (Plaintiffs' Exhibit A pp.38, 43-44). No instructions are provided regarding the set-up, or administration of either more, or less, than 100 ml of pentobarbital solution.

41. The Lethal Injection Protocol allows "the chemical manufacturer [to] change the concentration of the chemical solution without notification" (Plaintiffs' Exhibit A p.36).

42. The only commercially-available source of pentobarbital is sold under the brand name of Nembutal®.

43. In July of 2011, Lundbeck instituted distribution controls to prevent the legitimate sale of Nembutal® to departments of corrections in states that use lethal injection for capital punishment.

44. In December, 2011, Lundbeck sold its interests in Nembutal® to Akorn Pharmaceuticals ("Akorn").

45. The only current FDA-approved source of Nembutal® is Akorn. Akorn has retained Lundbeck's distribution controls.

46. All stocks of Nembutal® sold prior to the institution of the Lundbeck/Akorn controls have expired.

47. Defendants therefore have no legitimate and/or legal source of Nembutal®.

48. Any pentobarbital to be used in executing Plaintiffs will come from either: (a) the illegal importation of pentobarbital, a Schedule II controlled substance; or, (b) the compounding of pentobarbital by the “licensed pharmacy or pharmacist” set forth in the Lethal Injection Protocol (Plaintiffs’ Exhibit A p.36).

49. In the past, Tennessee has obtained illegally-imported drugs for use in lethal injection.

50. Tennessee’s prior attempts to maintain possession of illegally imported drugs for use in executions have failed.

51. On March 22, 2011, Tennessee Department of Correction remitted its entire supply of illegally imported Sodium Thiopental, a barbiturate and Class II controlled substance that it had acquired for the purposes of carrying out Tennessee’s then three-drug protocol to federal law enforcement.

52. On March 27, 2012, the United States District Court for the District of Columbia enjoined the federal Food and Drug Administration from permitting the Tennessee Department of Correction to acquire additional illegally imported Sodium Thiopental. *Beaty, et al. v. Food and Drug Administration, et al.*, No. 1:11-cv-00289-RJL, Docket Entry 24. That decision was affirmed on July 23, 2013. *Cook v. Food and Drug Administration*, 733 F.3d 1 (D.C. Cir. 2013).

53. Accordingly, Defendants cannot lawfully obtain and/or possess illegally imported pentobarbital for use in the Lethal Injection Protocol.

54. It is therefore alleged upon information and belief that Defendants will use compounded pentobarbital to execute Plaintiffs.

55. Compounding rules prohibit the duplication of commercially-available drugs.
56. The commercially available source of pentobarbital, Nembutal[®], is available in a concentration of 50 mg/ml.
57. Though the Lethal Injection Protocol calls for the administration of 5 grams of pentobarbital, the “chemical manufacturer” has unlimited discretion to, and is likely to, supply pentobarbital in a solution other than 50 mg/ml (Plaintiffs’ Exhibit A p.36).
58. The “chemical manufacturer” may change the amount of pentobarbital the Plaintiffs will receive without notice to either the other Defendants (Plaintiffs’ Exhibit A p.36) or the Plaintiffs.
59. If Defendants adhere to the Lethal Injection Protocol, there is a substantial risk that Plaintiffs will receive an amount of pentobarbital other than the 5 grams required under the protocol.
60. If the Executioners adhere to the Lethal Injection Protocol, there is a substantial risk that Plaintiffs will receive an amount of pentobarbital unknown to Plaintiffs at any meaningful time before the Plaintiffs’ executions.
61. The Lethal Injection Protocol does not address an individual prisoner’s weight, medical condition and medical history as related to the dosage and/or method of administration of pentobarbital.
62. The Lethal Injection Protocol directs the Execution Team to bring the lethal injection chemicals to the Lethal Injection Room prior to an execution. Each chemical is prepared for being drawn into syringes (Plaintiffs’ Exhibit A p.38).

63. Under the Lethal Injection Protocol, the following lethal injection chemicals are drawn into three syringes:

- a. Syringe 1 (red) pentobarbital (50cc)
- b. Syringe 2 (red) pentobarbital (50 cc)
- c. Syringe 3 (red) saline

(Plaintiffs' Exhibit A pp.38, 44).

64. A second set of syringes (*i.e.*, the "blue" set) is not prepared "unless the primary dose proves insufficient." (Plaintiffs' Exhibit A p.38).

65. No time frame is given regarding administration of the drugs (Plaintiffs' Exhibit A p.44).

66. Under the Lethal Injection Protocol, two IV lines are prepared for simultaneous use. First, the prisoner's arms are securely restrained to the gurney. A tourniquet is placed around the limb or body part above the vein to be used. The Lethal Injection Protocol does not instruct or designate a person to remove the tourniquet. The IV Team inserts a catheter into the right arm, in the antecubital fossa area, and attaches a Solution Set line from a sodium chloride bag (located in the lethal injection room) to the catheter (Plaintiffs' Exhibit A pp.41-42).

67. The Lethal Injection Protocol contains other locations for insertion of the catheter if it cannot be inserted into a vein in the antecubital fossa area. The order of the locations is: forearm, wrist, back of the hand, top of the foot, ankle, lower leg, or other locations as determined by the EMTs (Plaintiffs' Exhibit A p.41).

68. The Lethal Injection Protocol directs that if “none of these veins are usable, the physician is called into the Execution Chamber to perform a cut-down procedure” (Plaintiffs’ Exhibit A p.41). Prior to this, the Physician waits in the capital punishment garage (Plaintiffs’ Exhibit A p.20). The Lethal Injection Protocol alleges that a cut-down is “an ultimate and last option” (Plaintiffs’ Exhibit A p.20) but also allows the Physician to “choose[] a different method to find an IV site” (Plaintiffs’ Exhibit A p.67). The Lethal Injection Protocol is silent as to the Physician’s qualifications, training and experience to perform such functions.

69. The Lethal Injection Protocol does not recommend the shortest possible length for the IV setup. Instead, it indicates that the Solution Sets are 85 inches long but may be purchased longer or shorter; extensions into the first port should be 18 to 24 inches in length; extensions are added to each end of the Solution Set until it reaches the desired length; the ends should reach from head to toe of the condemned inmate (Plaintiffs’ Exhibit A p.40).

70. Under the Lethal Injection Protocol, the IV line is connected to the catheter via extensions “added to each end . . . until it reaches the desired length” (Plaintiffs’ Exhibit A p.40). “The line is taped to the port (where the syringe is inserted) in place. The remainder of the line is placed out of the ports in the window[]” of the Lethal Injection Room and taped in place (Plaintiffs’ Exhibit A p.40). Tegaderm transparent dressing is placed over the catheter and the line is taped in place (Plaintiffs’ Exhibit A p.42).

71. Under the Lethal Injection Protocol, the process is repeated for the left arm (Plaintiffs’ Exhibit A pp.41-42). Then the inmate’s hands are taped in place, palms up, and the IV Team Members leave the Execution Chamber (Plaintiffs’ Exhibit A p.43).

72. Under the Lethal Injection Protocol, the Warden is the only person in the Execution Chamber with the condemned prisoner.

73. Under the Lethal Injection Protocol, the Warden gives the signal to proceed with the execution. The Executioner chooses the right or left IV line. The Executioner inserts and twists the first syringe (# 1 red) into the extension line (Plaintiffs' Exhibit A p.43). The Executioner then pushes the plunger of the #1 red with "slow, steady pressure" (Plaintiffs' Exhibit A p.44). Should there be or appear to be swelling around the catheter or if there is resistance to the pressure being applied to the plunger, the Executioner pulls the plunger back. If the extension line starts to fill with blood, the execution may proceed. If there is no blood, the Executioner discontinues with this line. He starts the process on the other line with the back-up set of syringes starting with syringe # 1 (blue) (Plaintiffs' Exhibit A p.44).

74. No instructions are provided to the Executioner regarding the injection of the second syringe (#2 red), or the injection of the third syringe (#3 red). However, the IV team members are to hand him the syringes and observe him as he injects them. After the third syringe has been injected, the Executioner is to open the line and allow a drop of 1-2 drops/second into the drip chamber (Plaintiffs' Exhibit A p.44).

75. Under the Lethal Injection Protocol, after a five-minute waiting period, the Warden summons the Physician to determine if the prisoner is dead (Plaintiffs' Exhibit A p.65). Though the Lethal Injection Protocol does not state how the Physician makes this determination, Plaintiffs are informed and therefore believe that it is done by using a stethoscope to determine whether a heartbeat is present.

76. If the Physician states that the prisoner is not dead, the process is repeated (Plaintiffs' Exhibit A p.67).

77. If the Physician states that the prisoner is dead, his body is provided to the Medical Examiner and transported to State Medical Examiner for "examination" and release. (Plaintiffs' Exhibit A p.65-66). Although the protocol is silent regarding whether the "examination" includes an autopsy, Defendants' past practice is to perform an autopsy of the body shortly after the execution unless an objection has been lodged.

COUNT I

VIOLATION OF THE EIGHTH AND FOURTEENTH AMENDMENTS OF THE UNITED STATES CONSTITUTION AND TENNESSEE CONSTITUTION ARTICLE 1, § 16 THROUGH ADHERENCE TO THE LETHAL INJECTION PROTOCOL WHICH CREATES A SUBSTANTIAL RISK OF UNNECESSARY PAIN WHEN CARRIED OUT EXACTLY IN THE MANNER PRESCRIBED

78. The Lethal Injection Protocol calls for two bolus injections of 2.5 grams of the barbiturate pentobarbital in rapid succession. No other drugs or active chemical ingredients are injected.

79. Barbiturates, such as pentobarbital, do not act directly to stop the heart, but rather, create a state known as hypoxia that, in turn, will eventually cause the cessation of rhythmic electrical activity in the heart, *i.e.*, death.

80. Two bolus injections of 2.5 grams of barbiturate in rapid succession is likely to cause hypoxia.

81. There is a substantial risk that the period of hypoxia caused by two bolus injections of 2.5 grams of barbiturate in rapid succession will not be sufficiently long to cause the cessation of electrical activity in the heart. In other words, Plaintiffs will not die.

82. The period of time required to cause the cessation of electrical activity in the heart (*i.e.*, death) through hypoxia is extremely difficult to predict.

83. The period of time required to cause the cessation of electrical activity in the heart (*i.e.*, death) through hypoxia can be markedly prolonged.

84. The time required to cause the cessation of electrical activity in the heart (*i.e.*, death) through hypoxia can be, and often is, longer than five minutes.

85. Even when the period of hypoxia is not sufficiently long to cause the cessation of electrical activity in the heart (*i.e.*, death), hypoxia will cause the heart to stop beating.

86. When the period of hypoxia is not sufficiently long to cause the cessation of electrical activity in the heart (*i.e.*, death), but long enough to cause the heart to stop beating, a heartbeat will not be present even though Plaintiffs are alive.

87. There is a substantial risk that, five minutes after the pentobarbital has been administered, Plaintiffs will have experienced hypoxia for a sufficient amount of time to cause the heart to stop beating, yet too short of a time to cause the cessation of electrical activity in the heart (*i.e.*, death).

88. There is a substantial risk that when Defendant Physician checks for Plaintiffs' heartbeat, as required by the Lethal Injection Protocol, the Plaintiffs will have experienced

hypoxia for a sufficient amount of time to cause the heart to stop beating, yet too short of a time to cause the cessation of electrical activity in the heart (*i.e.*, death).

89. Under the circumstances described in the preceding paragraph, Defendant Physician will incorrectly declare Plaintiffs “deceased,” even though they have not experienced the cessation of electrical activity in the heart and are still alive (Plaintiffs’ Exhibit A p.20).

90. According to the Lethal Injection Protocol, should Defendant Physician pronounce Plaintiffs “deceased,” they will not receive a second dose of pentobarbital but instead will be removed from the execution chamber and transported to the State Medical Examiner for examination (*i.e.*, autopsy) (Plaintiffs’ Exhibit A p.20).

91. If after five minutes Plaintiffs have neither experienced hypoxia for a sufficient amount of time to cause the heart to stop beating, nor for a sufficient amount of time to cause the cessation of electrical activity in the heart (*i.e.*, death), Defendant Physician may detect Plaintiffs’ heartbeat.

92. Under the circumstances described in the preceding paragraph, the Lethal Injection Protocol calls for the administration of two additional bolus injections of 2.5 grams of pentobarbital in rapid succession (Plaintiffs’ Exhibit A pp.44, 65, 67).

93. Under the Lethal Injection Protocol, the second set of two syringes each containing 2.5 grams of pentobarbital is not prepared before the execution begins (Plaintiffs’ Exhibit A p.39).

94. Under the circumstances described in the previous three paragraphs, there is a substantial risk that Plaintiffs will experience hypoxia, but not the cessation of electrical activity in the heart (*i.e.*, death), even after the administration of the second set of syringes.

95. There is a substantial risk that Plaintiffs who have been hypoxic for a period of time sufficient to stop the heart, but not to cause the cessation of electrical activity in the heart (*i.e.*, death), will suffer severe and permanent damage to the brain and other organs.

96. Inflicting severe and permanent, but not immediately fatal, damage to Plaintiffs' brain and/or other organs through a period of hypoxia insufficient to cause the cessation of electrical activity in the heart (*i.e.*, death) violates the Eighth and Fourteenth Amendments to the United States Constitution and Tennessee Constitution Article 1, § 16.

97. A Lethal Injection Protocol that causes death over a prolonged period of time by inflicting severe and permanent, but not immediately fatal, damage to Plaintiffs' brain and/or other organs violates the Eighth and Fourteenth Amendments to the United States Constitution and Tennessee Constitution Article 1, § 16.

98. A Lethal Injection Protocol that requires the examination (*i.e.*, autopsy) of Plaintiffs who have incorrectly been pronounced "deceased" by Defendant Physician violates the Eighth and Fourteenth Amendments to the United States Constitution and Tennessee Constitution Article 1, § 16.

99. There is a substantial risk that Plaintiffs who have suffered severe and permanent damage to the brain and/or other organs, but have not died, will be rendered incompetent under *Panetti v. Quarterman*, 551 U.S. 930 (2007) and *Ford v. Wainwright*, 477 U.S. 399 (1986), and

any subsequent attempt to execute the Plaintiffs, regardless of means, violates the Eighth and Fourteenth Amendments to the United States Constitution and Tennessee Constitution Article 1, § 16.

100. Defendant Schofield (and/or one or more other Defendants) knew or should have known each fact alleged in this Count, but has acted with deliberate indifference to the same.

101. The Lethal Injection Protocol therefore violates the Eighth and Fourteenth Amendments to the United States Constitution and Tennessee Constitution Article 1, § 16.

102. By adhering to the Lethal Injection Protocol, Defendants will violate the Eighth and Fourteenth Amendments to the United States Constitution and Tennessee Constitution Article 1, § 16, and 42 U.S.C. § 1983.

COUNT II

VIOLATION OF THE EIGHTH AND FOURTEENTH AMENDMENTS TO THE UNITED STATES CONSTITUTION AND TENNESSEE CONSTITUTION ARTICLE 1, § 16 THROUGH ADHERENCE TO THE LETHAL INJECTION PROTOCOL WHICH WILL REQUIRE THE USE OF COMPOUNDED PENTOBARBITAL

103. Plaintiffs incorporate the preceding paragraphs in their entirety.

104. The only FDA-approved source of pentobarbital, a Schedule II drug, is sold under the brand name Nembutal®.

105. At all times relevant hereto until December of 2011, the only FDA-approved source of Nembutal® was the pharmaceutical company Lundbeck ("Lundbeck").

106. In July of 2011, Lundbeck instituted distribution controls to prevent the legitimate sale of Nembutal® to departments of corrections in states that use lethal injection for capital punishment.

107. In December, 2011, Lundbeck sold its interests in Nembutal® to Akorn Pharmaceuticals (“Akorn”).

108. The only current FDA-approved source of Nembutal® is Akorn. Akorn has retained Lundbeck’s distribution controls.

109. All stocks of Nembutal® sold prior to the institution of the Lundbeck/Akorn controls have expired.

110. Defendants therefore have no legitimate and/or legal source of Nembutal®.

111. Any pentobarbital to be used in executing Plaintiffs will come from either: (a) the illegal importation of pentobarbital, a Schedule II controlled substance; or, (b) the compounding of pentobarbital by the “licensed pharmacy or pharmacist” set forth in the Lethal Injection Protocol (Plaintiffs’ Exhibit A p.36).

112. In the past, Tennessee has obtained illegally-imported drugs for use in lethal injection.

113. On March 22, 2011, Tennessee Department of Correction remitted its entire supply of illegally imported Sodium Thiopental, a barbiturate and Class II controlled substance that it had acquired for the purposes of carrying out Tennessee’s then three-drug protocol federal law enforcement.

114. On March 27, 2012, the United States District Court for the District of Columbia enjoined the federal Food and Drug Administration from permitting the Tennessee Department of Correction to acquire additional illegally imported Sodium Thiopental. *Beatty, et al. v. Food and Drug Administration, et al.*, No. 1:11-cv-00289-RJL, Docket Entry 24. That decision was affirmed on July 23, 2013. *Cook v. Food and Drug Administration*, 733 F.3d 1 (D.C. Cir. 2013).

115. Accordingly, Defendants cannot lawfully obtain and/or possess illegally imported pentobarbital for use under the Lethal Injection Protocol.

116. It is therefore alleged upon information and belief that Defendants will use compounded pentobarbital to execute Plaintiffs.

A.

THERE IS A SUBSTANTIAL RISK THAT DEFENDANTS' WILL USE APIs FROM NON-FDA-APPROVED SOURCES IN THE COMPOUNDING OF PENTOBARBITAL FOR USE IN THE LETHAL INJECTION PROTOCOL THEREBY PRODUCING PENTOBARBITAL THAT IS NON-STERILE, IMPURE, ADULTERATED, SUB-POTENT, AND/OR COUNTERFEIT

117. Plaintiffs incorporate the preceding paragraphs in their entirety.

118. Traditional pharmacy compounding is a practice of the profession of pharmacy that uses Active Pharmaceutical Ingredients (APIs) and inactive ingredients obtained from FDA-approved facilities to meet the individual needs of a patient that cannot be met with an FDA-approved product.

119. A substantial percentage of compounding is performed by pharmacists who compound APIs and inactive ingredients obtained from non-FDA-approved facilities. This non-traditional compounding occurs within what is known as the "grey market."

120. Though Defendants have refused to reveal information regarding the source of pentobarbital to be used under the Lethal Injection Protocol, there is a substantial risk that Defendants will use pentobarbital from a source, *i.e.* Defendant Pharmacist(s), that compounds APIs obtained from non-FDA-approved facilities, *i.e.*, on the grey market.

121. There is a substantial risk that the APIs obtained on the grey market in order to compound pentobarbital for use in the Lethal Injection Protocol are impure, adulterated, sub-potent, and/or counterfeit.

122. There is a substantial risk that grey market APIs will come from plants in China, India, and/or other countries lacking the oversight and control necessary to produce uncontaminated, unadulterated, fully potent, and genuine APIs.

123. Plants in China providing APIs to the grey market have manufactured pesticides using the same equipment that is used to make APIs.

124. Several studies, including a survey conducted by the FDA in 2001, report a high prevalence of quality problems with various pharmacy-compounded drugs, including sub-potency and contamination.

125. A survey of compounded drug products was conducted by the FDA in 2006 to explore these issues further. The results showed that thirty-three percent of the compounded drugs failed analytical testing using rigorously defensible testing methodology.

126. Testing by the Missouri Board of Pharmacy, which is the only state that regularly tests compounded drugs, reveals that compounded drugs fail tests for potency and purity on average around twenty-five percent of the time.

127. Defendants are unable to reduce said substantial risk because: (a) the manufacturer of the APIs are unknown; (b) the impurity profile of the APIs are unknown; and (c) the age, storage, the manufacturing environment, or the manufacturing method of the APIs are unknown.

128. Chemicals that have not have been manufactured in an FDA-registered facility under current Good Manufacturing Practices, have no assurance as to the quality variation from lot to lot or from container to container.

129. Within the grey market, secondary sources of APIs, *e.g.*, wholesalers and/or distributors, frequently use ambiguous and/or false statements in marketing APIs.

130. Statements from such secondary sources provide no reliable assessment of the purity, potency, identity, and/or lack of contamination of grey market APIs.

131. Intrinsic or extrinsic contaminants can be introduced during chemical manufacture or at any point during the chemical's synthesis.

132. There is a substantial risk that, Defendant Pharmacist is not capable of conducting testing to confirm the identity of the chemical and/or to identify the presence of harmful contaminants that pose an immediate safety threat if administered intravenously.

133. It is unknown whether the pharmacist intends to have either the active and inactive chemical ingredients, or the finished, compounded dosage form tested using robust methods of analysis.

134. Defendants, including, but not limited to, Defendant Pharmacist(s), do not have the ability to trace the APIs back to the original manufacturers for information on quality, packaging, storage, shipment conditions and chains of custody from a chemical's cradle to grave.

135. A compounded drug that is contaminated or is sub-potent, is unpredictable and potentially dangerous and therefore poses a substantial risk of pain and suffering to Plaintiffs when administered according to the Lethal Injection Protocol

B.

THERE IS A SUBSTANTIAL RISK THAT DEFENDANTS WILL USE PENTOBARBITAL COMPOUNDED BY A PHARMACY PRODUCING PENTOBARBITAL THAT IS NON-STERILE, IMPURE, ADULTERATED, AND/OR SUB-POTENT

136. Plaintiffs incorporate the preceding paragraphs in their entirety.

137. Pharmacy compounding is a practice by which a licensed pharmacist combines, mixes, or alters ingredients in response to a prescription to create a medication tailored to the medical needs of an individual patient.

138. Compounded drugs are not FDA-approved. This means that the FDA does not verify the quality, safety and effectiveness of compounded drugs. This also means that compounded drugs lack an FDA finding of manufacturing quality. Consumers and health professionals rely on the drug approval process to ensure that drugs are safe and effective.

139. Though Defendants have withheld information regarding the source of pentobarbital to be used under the Lethal Injection Protocol, it is very likely that Defendant Pharmacist(s) will compound pentobarbital in a pharmacy or pharmacies located within the State of Tennessee.

140. Tennessee law regulates the process of compounding by defining what compounding means and requiring licensing.

141. Pentobarbital for injections may be compounded only in a “sterile” compounding facility.

142. It is unknown whether Defendants will obtain compounded pentobarbital from a pharmacy, manufacturer, and/or wholesaler/distributor that possesses a sterile compounding registration.

143. It is unknown whether Defendants will obtain compounded pentobarbital from a sterile compounding facility.

144. It is unknown whether Defendants will obtain compounded pentobarbital from a manufacturer registered with the FDA.

145. Sterile compounding pharmacies located within the State of Tennessee are subject to certain federal and state regulations and relevant United States Pharmacopeia guidelines as adopted by the Tennessee Board of Pharmacy by rule or policy. *See, e.g.*, Tenn. Code Ann. § 63-10-216(c).

146. Though Tennessee law requires sterile compounding pharmacies to report all compounding activity, the State of Tennessee currently maintains no list of such pharmacies, nor of their activities.

147. Compounding pharmacies are not regularly inspected.

148. Errors that occur at compounding pharmacies may be caused by factors including:
(a) use of substandard or contaminated APIs; (b) use of an incorrect formula to prepare a

prescription drug; (c) maintenance of liquid dosages at inappropriately high temperatures, which may lead to chemical changes in the liquid; (d) failure to maintain a sterile facility and/or procedures; (e) failure to maintain manufacturing equipment in a sterile manner; (f) failure to properly store compounded products; (g) mislabeling medication; and (h) labeling medication with improper dispensing instructions for patient use.

149. When errors occur in compounding sterile preparations, including pentobarbital, harm can result from microbial contamination, excessive bacterial endotoxins, variability in intended strength, unintended chemical and physical contaminants, and ingredients of inappropriate quality.

150. In 2013, the FDA inspected certain pharmacies that were known to have produced high-risk sterile drug products in the past and posed a significant threat to public health from poor sterile drug production practices. The FDA issued inspectional observations of sterile production issues to all 28 pharmacies engaged in sterile compounding that were inspected.

151. The 2013 FDA inspection of two Tennessee pharmacies revealed issues including inadequate sterilization to prevent contamination, a lack of testing of the product for identity, strength, quality and purity, and improper storage to prevent contamination.

152. It is unknown whether Defendants will obtain compounded pentobarbital from a pharmacy that has issues similar to those described in the above paragraph.

153. In one of the three (*i.e.*, in 33% of) one-drug protocol executions carried out with compounded pentobarbital, the South Dakota execution of Eric Robert, post-execution analysis of the compounded pentobarbital revealed that the drug was contaminated by fungus. It took Mr.

Robert twenty minutes to die. During the course of his execution, he opened his eyes and they remained open until his death.

154. A 33% error rate in a one-drug compounded pentobarbital lethal injection execution constitutes a substantial risk of serious harm.

C.

DEFENDANTS' USE OF PENTOBARBITAL OF A DIFFERENT CONCENTRATION THAN REQUIRED IN THE LETHAL INJECTION PROTOCOL CREATES A SUBSTANTIAL RISK OF UNNECESSARY PAIN AND SUFFERING

155. The Lethal Injection Protocol specifies that the inmate is to be injected with 100ml of the barbiturate, pentobarbital, in a 50mg/ml solution, for a total of 5 grams of pentobarbital (Plaintiffs' Exhibit A p.35).

156. Compounding rules prohibit the duplication of commercially-available drugs.

157. The commercially available source of pentobarbital, Nembutal[®], is available in a concentration of 50 mg/ml.

158. The compounded pentobarbital obtained by Defendants for use in the Lethal Injection Protocol will not have a concentration of 50 mg/ml.

159. If Defendants use pentobarbital with a concentration of less than 50 mg/ml, there is a substantial risk that Plaintiffs will be administered less than the amount of pentobarbital set forth in the Lethal Injection Protocol.

160. Defendants use of pentobarbital with a concentration of less than 50 mg/ml, increases the already substantial risk that the Plaintiffs will not receive an adequate dose of

pentobarbital, and that the cessation of electrical activity in the heart (*i.e.*, death) will not occur, thereby inflicting unnecessary pain.

D.

DEFENDANTS' USE OF NON-STERILE, IMPURE, ADULTERATED, SUB-POTENT, AND/OR COUNTERFEIT PENTOBARBITAL IN THE LETHAL INJECTION PROTOCOL CREATES A SUBSTANTIAL RISK OF UNNECESSARY PAIN AND SUFFERING

161. Plaintiffs incorporate the preceding paragraphs in their entirety.

i. Bacterial and fungal contamination

162. Both bacteria and fungus are among the impurities commonly found in compounded injectable drugs such as pentobarbital.

163. Bacterial and/or fungal contamination will alter important attributes of the pentobarbital used in Plaintiffs' executions, including final pH.

164. There is a substantial risk that alteration of the final pH of the pentobarbital used in Plaintiffs' executions will create instability and/or incompatibility with human blood.

165. There is a substantial risk that, should the pH of the pentobarbital used in Plaintiffs' executions be incorrect, Plaintiffs will experience a burning sensation as it is being injected.

166. There is a substantial risk that, should the pH of the pentobarbital used in Plaintiffs' executions be incorrect, it could form precipitates, or solid particles, of drug and other substances.

167. Should solid, particulate matter of any kind be present in the pentobarbital used to execute the Plaintiffs, there is a substantial risk that Plaintiffs will suffer unnecessary pain and suffering upon injection of the solution, including, but not limited to, the pain associated with a pulmonary embolism.

168. Bacterial and/or fungal contamination in compounded injectable solution produces endo-toxins and/or exo-toxins.

169. Endo-toxins and/or exo-toxins contained in compounded injectable solution can cause immediate and painful reactions associated with septic shock, including, but not limited to, a sudden rise in body temperature, a precipitous drop in blood pressure and seizure.

170. Should endo-toxins and/or exo-toxins be present in the pentobarbital used to execute the Plaintiffs, there is a substantial risk that Plaintiffs will suffer unnecessary pain and suffering upon injection of the solution.

171. Bacteria and/or fungi commonly found in compounded injectable solution are growing organisms.

172. The presence of growing organisms accelerates chemical degradation.

173. Chemical degradation decreases the potency of injectable solutions such as pentobarbital.

174. Should bacterial and/or fungal contamination reduce the potency of the pentobarbital used to execute Plaintiffs, there is a substantial risk Plaintiffs will not receive an adequate dose of pentobarbital and that the cessation of electrical activity in the heart (*i.e.*, death) will not occur, thereby inflicting unnecessary pain. *See Count One.*

ii. Contamination by particulate matter

175. Contamination with particulate matter is also common in compounded injectable drugs.

176. Should solid, particulate matter of any kind be present in the pentobarbital used to execute the Plaintiffs, there is a substantial risk that Plaintiffs will suffer unnecessary pain and suffering upon injection of the solution, including, but not limited to, the pain associated with a pulmonary embolism.

iii. Sub-potency

177. Larger than expected moisture content is common in grey market APIs.

178. Larger than expected moisture content results in inaccurate weighing of the API and a smaller amount of the API will be used for the compounding of the pentobarbital for Plaintiffs' executions.

179. Should a smaller amount of the API be used to compound the pentobarbital, there is a substantial risk that the pentobarbital for Plaintiffs' executions will be sub-potent.

180. The substantial risk that the compounded pentobarbital will not be the concentration required under the Lethal Injection Protocol due to the use of APIs obtained from non-FDA-approved facilities increases the already substantial risk that the Plaintiffs will not receive an adequate dose of pentobarbital and the cessation of electrical activity in the heart (*i.e.*, death) will not occur, thereby inflicting unnecessary pain.

181. The Defendants have withheld information under Tennessee Statute § 10-7-504 regarding the source and procurement of the pentobarbital (lethal injection drug(s)) they intend to

use to execute Plaintiffs. As set forth *infra*, at Claim VIII, the statute, and Defendants' reliance on the statute, denies Plaintiffs their right to meaningful access to the courts under the Constitutions of the United States and the State of Tennessee. Plaintiffs reserve the right to amend this claim following discovery of information regarding the source and procurement of the lethal injection drug(s) they intend to use to execute the Plaintiffs.

182. The Lethal Injection Protocol will require the use of compounded pentobarbital. As a result, it increases the already substantial risk that Plaintiffs will not receive an adequate dose of pentobarbital and the cessation of electrical activity in the heart (*i.e.*, death) will not occur, and Plaintiffs will suffer unnecessary pain. It also creates a substantial risk that Plaintiffs will suffer additional unnecessary pain as set forth within this claim.

183. Defendant Schofield (and/or one or more other Defendants) knew or should have known each fact alleged in this Count and they have acted and/or continue to act, with deliberate indifference to the same.

184. The Lethal Injection Protocol therefore violates the Eighth and Fourteenth Amendments to the United States Constitution and Tennessee Constitution Article 1, § 16.

185. By adhering to the Lethal Injection Protocol, Defendants will violate the Eighth and Fourteenth Amendments to the United States Constitution and Tennessee Constitution Article 1, § 16 and 42 U.S.C. § 1983.

COUNT III

**VIOLATION OF THE EIGHTH AND FOURTEENTH AMENDMENT AND TENNESSEE CONSTITUTION
ARTICLE 1, § 16 THROUGH ADHERENCE TO THE LETHAL INJECTION PROTOCOL WHICH FAILS
TO PROVIDE ADEQUATE QUALIFICATIONS AND TRAINING OF PERSONNEL TO MINIMIZE THE
KNOWN RISKS INVOLVED IN EXECUTION BY LETHAL INJECTION**

186. Plaintiffs incorporate the preceding paragraphs in their entirety.

187. Defendants' selection, education, and training of persons directly involved in the lethal injection process as set forth in the Lethal Injection Protocol does not render them capable of carrying out their duties. The use of such persons creates the risk of unnecessary pain and suffering; does not conform with evolving standards of decency; and evinces deliberate indifference to minimizing known risks. *City of Canton v. Harris*, 489 U.S. 378, 388 (1989).

188. The Lethal Injection Protocol states "[t]he Execution Team simulates Day 3 (Execution Day) . . . for at least one (1) hour each month" (Plaintiffs' Exhibit A p.33).

189. After the one-drug Lethal Injection Protocol was adopted, Defendants simulated the old, three-drug protocol.

190. Defendants' failure to simulate the current Lethal Injection Protocol constitutes a substantial risk of serious harm to Plaintiffs.

191. Defendants' failure to follow the Lethal Injection Protocol constitutes a substantial risk of serious harm to Plaintiffs.

192. The Lethal Injection Protocol fails to describe the members of the IV Team, however, it designates seven members of the Execution Team as "specialized" and as having "specific requirements." *See* Plaintiffs' Exhibit A p.32. Five such members have specific roles

in administering pentobarbital to the condemned inmate. They are hereinafter referred to as the "IV Team."

193. The five members of the IV team are:

- a. Two (2) EMTs - Paramedic - Certified Emergency Medical Technician[s] (hereinafter "EMTs"); and,
- b. Three (3) Correctional Officers - Received IV training through the Tennessee Correction Academy by qualified medical professionals (hereinafter "Executioners").

(Plaintiffs' Exhibit A p.32).

194. The State of Tennessee has three levels of "certification" for EMTs/Paramedics, each with different requirements, to wit:

EMT IV

1. Must submit a completed application for licensure.
2. Must be at least eighteen (18) years of age.
3. Must be able to read, write, and speak the English language.
4. Must possess an academic high school diploma or a general equivalency diploma (G.E.D.).
5. Must have no history within the past three years of habitual intoxication or personal misuse of any drugs or the use of intoxicating liquors, narcotics, controlled substances, or other drugs or stimulants in such manner as to adversely affect the person's ability to practice as an emergency medical technician.
6. Must present evidence to the Division of Emergency Medical Services of a medical examination certifying physical health sufficient to conduct activities associated with patient care, including, but not limited to, visual acuity, speech and hearing, use of all extremities, absence of musculoskeletal deformities, absence of communicable diseases, and suitable emotional fitness to provide for the care and lifting of the ill or injured. This information shall be provided on a form approved by the Board and shall be consistent with the provisions of the Americans with

Disabilities Act and the requirements of National Registry of Emergency Medical Technicians. Must successfully complete an EMS Board approved Emergency Medical Technician Basic IV course.

7. Must achieve a passing score on a EMS Board approved written examination.
8. Must successfully complete an EMS Board approved practical examination.
9. Must complete a criminal background check from the State approved vendor.
10. Must pay all required application and license fees.
11. Must complete entire license process within two years of course completion.

Paramedic

1. Must submit a completed application for Licensure.
2. Must meet all the Emergency Medical Technician IV licensure requirements.
3. Must have successfully completed an EMS Board approved EMT Paramedic course.
4. Must achieve a passing score on a Board approved written examination.
5. Must have successfully completed an EMS Board approved practical examination.
6. Must complete a criminal background check from the State approved vendor.
7. Must pay all required application and license fees.
8. Must complete entire license process within two years of course completion.

Paramedic Critical Care

1. Must submit a completed application for Licensure.
2. Must be currently licensed as paramedic in good standing in Tennessee.
3. Must have successfully completed an EMS Board approved Critical Care Paramedic Program.
4. Must achieve a passing score on an EMS Board approved examination.
5. Must complete entire license process within two years of course completion.
6. Individuals completing a Critical Care Paramedic Course prior to effective date of this rule may make application for endorsement. Individuals must show documentation of completion of a Critical Care Paramedic Course and must achieve a passing score on an EMS Board approved examination. Individuals will have two (2) years to complete the examination requirements before being required to repeat the course.

(<https://health.state.tn.us/EMS/personnellicensure.htm>)

195. The Lethal Injection Protocol fails to indicate which, if any, of such certifications are required for the EMTs.

196. The Lethal Injection Protocol fails to indicate medical training, education, or licensing the EMTs must possess. The Lethal Injection Protocol does not require that the EMTs be qualified in any particular way, other than “certification.” *See* Plaintiffs’ Exhibit A p.32. The Lethal Injection Protocol does not require the EMTs to be trained, and/or skilled, and/or experienced in IV access procedures (Plaintiffs’ Exhibit A p.32).

197. Under the Lethal Injection Protocol, the EMTs have duties that are critical to preventing the infliction of unnecessary pain and suffering during Plaintiffs’ execution.

198. Failure in the EMTs’ performance of their duties will result in a substantial risk of unnecessary pain.

199. There is a risk that a person inserting an IV might get “false positives” showing that an IV was inserted properly when, in fact, it was not.

200. Under the Lethal Injection Protocol swelling might not occur in surrounding tissue, and other signs of “infiltration” might not be present, thus, making detection of the improper insertion of the IV line unlikely.

201. Under the Lethal Injection Protocol, such errors could not be detected by remote visual observation of the injection site, especially at the antecubital fossa.

202. In past practice, the IV Team members (including the EMTs) and the Executioners were “largely ignorant” about reliable ways to detect infiltration.

203. If infiltration occurs, Plaintiffs will not receive a full dose of pentobarbital.

204. If Plaintiffs do not receive a full dose of pentobarbital, there is a substantial risk that they will suffer damage to the brain and/or organs, and will not die.

205. The infliction of permanent damage to the brain and/or organs of the Plaintiffs constitutes cruel and unusual punishment.

206. Death slowly caused by a prolonged period of brain and/or organ damage constitutes cruel and unusual punishment.

207. Because undetected infiltration increases the substantial risk that the Plaintiffs will not receive an adequate dose of pentobarbital to cause the cessation of electrical activity in the heart (*i.e.*, death), Defendants' adherence to the Lethal Injection Protocol that fails to provide for adequate qualifications and training of the EMTs to minimize the known risks involved in execution by lethal injection violates the Eighth and Fourteenth Amendment and Tennessee Constitution Article 1, § 16.

208. The Lethal Injection Protocol fails to indicate what instruction the Executioner receives, by whom that instruction is given, and what qualifications, education, training, licensing and screening that individual has to provide any such instruction. The Lethal Injection Protocol only says that "[t]he Executioner receives initial and periodic instruction from a qualified medical professional" (Plaintiffs' Exhibit A p.33).

209. The Lethal Injection Protocol fails to indicate what training is required for members of the Execution Team. *See* Plaintiffs' Exhibit A p.33. The Lethal Injection Protocol only indicates that Execution Team members are required to read the manual and that "[t]he Warden or his designee holds a class during which the manual is reviewed and clearly understood by all participants" (Plaintiffs' Exhibit A p.33).

210. The Lethal Injection Protocol does not explain how the Warden ensures that the manual is clearly understood by all participants nor does it explain who teaches the science and medical techniques to be utilized in the manual (Plaintiffs' Exhibit A p.33).

211. The Lethal Injection Protocol fails to provide training and instructions for using the shortest amount of tubing, extensions and junctions for the IV set-up which will reduce problems associated with blockages, kinks, *etc.*, in the lines.

212. The Lethal Injection Protocol fails to indicate what kind of junctures are used in the tubing, what kind of stopcock is used, or the size of the IV catheter.

213. The Lethal Injection Protocol fails to provide training and specific instructions regarding the effects of pentobarbital and its known risks.

214. Under the Lethal Injection Protocol, Executioners who feel "resistance to the pressure being applied to the plunger" are required to check to determine whether the IV catheter has remained in the vein throughout the execution process (Plaintiffs' Exhibit A, pp.43-44).

215. The "check" described in the previous paragraph provides the only method of determining whether the IV catheter has remained in the vein throughout the execution process.

216. Under the Lethal Injection Protocol, training is conducted with saline and not pentobarbital (Plaintiffs' Exhibit A p.33).

217. Pentobarbital and saline are of different viscosity.

218. Because the Executioners have not trained using pentobarbital and/or a liquid of similar viscosity, they are unaware of what resistance is normal.

219. Because the executioners do not know what resistance is normal during an IV push of pentobarbital, a “check” dependent upon resistance is ineffective to determine whether the IV catheter has not remained in the vein.

220. There is a substantial risk that an initially properly inserted catheter will slip from the vein during the pentobarbital injections.

221. There is a risk that a person inserting an IV might get “false positives” showing that an IV was inserted properly when, in fact, it was not.

222. Expert testimony in *Harbison v. Little*, 511 F. Supp. 2d 872 (M.D. Tenn. 2007), *vacated and remanded Harbison v. Little*, 571 F.3d 531 (6th Cir. 2009), showed that IV catheters do move “with a fairly high frequency,” from veins into outer tissue even in a clinical setting. *Id.* at 889.

223. Dr. Dershwitz, an expert witness for the State of Tennessee in *Harbison*, stated that “[s]ometimes intravenous catheters fail’ and that if the only individuals who are trained in monitoring IV lines leave the room following insertion of the catheters--which is what the new protocol dictates--he ‘think[s] it is logical to assume that there’s an increased risk.’” *Id.* at 888.

224. IV disruption is much more likely to occur under Tennessee’s protocol where the untrained Executioners administer large amounts of bolus injections, from far away, through long IV lines, “‘without direct visual contact and without tactile contact,’ all of which [are] ‘set-ups for failure and mistakes.’” *Id.* at 889.

225. Under the Lethal Injection Protocol, the Executioners are responsible for the preparation and administration of pentobarbital (Plaintiffs’ Exhibit A pp.38-39, 43-44).

226. The Lethal Injection Protocol requires that Plaintiffs are to be injected with 5 grams of pentobarbital (Plaintiffs' Exhibit A p.35).

227. The Lethal Injection Protocol provides instructions for the set-up and administration of 100 ml of pentobarbital solution (Plaintiffs' Exhibit A pp.38, 43-44).

228. The Lethal Injection Protocol allows "the chemical manufacturer [to] change the concentration of the chemical solution without notification" (Plaintiffs' Exhibit A p.36).

229. If the "chemical manufacturer" changes the concentration of the pentobarbital solution, 100ml of pentobarbital solution will not contain 5 grams of pentobarbital.

230. Administering less than 5 grams of pentobarbital constitutes a substantial risk that Plaintiffs will suffer brain and/or organ damage and not die.

231. If Plaintiffs do not receive a full dose of pentobarbital, there is a substantial risk that they will suffer damage to the brain and/or organs, and will not die.

232. The infliction of permanent damage to the brain and/or organs of the Plaintiffs constitutes cruel and unusual punishment.

233. The Lethal Injection Protocol provides no instructions regarding the set-up, or administration of either more, or less, than 100 ml of pentobarbital solution.

234. If the "chemical manufacturer" changes the concentration of the pentobarbital solution, the Lethal Injection Protocol provides no instructions regarding adjustments necessary to administer 5 grams of pentobarbital.

235. If the "chemical manufacturer" changes the concentration of the pentobarbital solution, the Executioners lack the skill, training, and expertise to adjustment as necessary to administer 5 grams of pentobarbital.

236. Because undetected infiltration will decrease the amount of pentobarbital effectively administered to Plaintiffs, it increases the substantial risk that Plaintiffs will not receive an adequate dose of pentobarbital.

237. Because of the Executioners' lack of skill, training, expertise, as well as the lack of instructions in the Lethal Injection Protocol, the likely event that the "chemical manufacturer" provides compounded pentobarbital in other than a 50mg/ml solution, will increase the already substantial risk that Plaintiffs will not receive an adequate and properly administered dose of pentobarbital.

238. Defendant Schofield (and/or one or more other Defendants) knew or should have known each fact alleged in this Count and they have acted and/or continue to act, with deliberate indifference to the same.

239. The Lethal Injection Protocol therefore violates the Eighth and Fourteenth Amendments to the United States Constitution and Tennessee Constitution Article 1, § 16.

240. By adhering to the Lethal Injection Protocol, Defendants will violate the Eighth and Fourteenth Amendments to the United States Constitution and Tennessee Constitution Article 1, § 16 and 42 U.S.C. § 1983.

COUNT VI

VIOLATION OF THE EIGHTH AND FOURTEENTH AMENDMENTS TO THE UNITED STATES CONSTITUTION AND TENNESSEE CONSTITUTION ARTICLE 1, § 16 THROUGH ADHERENCE TO THE LETHAL INJECTION PROTOCOL WHICH FAILS TO REQUIRE AND INCLUDE, AND FAILS TO COMPORT WITH, THOSE ACCEPTED MEDICAL PRACTICES NECESSARY TO MINIMIZE THE KNOWN RISKS INVOLVED IN EXECUTION BY LETHAL INJECTION

241. Plaintiffs incorporate the preceding paragraphs in their entirety.

242. The method of finding a suitable blood vessel and maintaining a flow through that blood vessel are considered to be medical matters. Standard medical methods and procedures have been developed that are required to minimize known risks inherent in those procedures.

243. The known risks inherent in the execution process including the IV set-up, location of veins, access to veins, insertion of catheters, monitoring and introduction of the pentobarbital are therefore minimized by adherence to such standard medical methods and procedures.

244. The Lethal Injection Protocol fails to minimize such risks because it does not adhere to such medical methods and procedures.

245. There is a substantial risk that persons performing the medical procedures incorporated into the Lethal Injection Protocol will be impaired during Plaintiffs' executions.

246. Persons with known alcohol and/or drug addictions have been allowed to participate in past Tennessee lethal injections.

247. The Lethal Injection Protocol fails to require drug and alcohol testing for participants in the execution, thus acting with deliberate indifference to a known risk that one or more such participants may be impaired while performing assigned duties.

248. Upon information and belief, the use of more than a single IV line at a time poses a substantial risk of error in the administration of intravenous drugs.

249. Should there be an error in the administration of pentobarbital during Plaintiffs' executions resulting in the administration of an inadequate amount of pentobarbital during Plaintiffs' executions, there is a substantial risk that Plaintiffs will suffer unnecessary and serious pain.

250. If venous access is inaccessible, whether from Plaintiffs' previous intravenous drug use or other reasons, the Lethal Injection Protocol utilizes a cut-down procedure.

251. A cut-down is an outdated, dangerous surgical procedure. *See Nelson v. Campbell*, 541 U.S. 637 642 (2004).

252. Engaging in a cut-down without first trying the less painful and less invasive method of percutaneous access represents a profound departure from standard medical methods and the standard of care used in executions in other states.

- a. The Lethal Injection Protocol indicates that a cut-down may be used but does not indicate at what point in the procedure the IV Team would resort to this option or who would make the determination that a cut-down is necessary.
- b. The Lethal Injection Protocol is silent as to the Physician's qualifications to perform a cut-down.
- c. Only 15% of physicians in the United States are qualified to perform a cut-down.
- d. Any cut-down procedure is a dangerous and antiquated medical procedure that is rarely performed in the practice of medicine.
- e. A cut-down procedure involves making a series of sharp incisions through the skin and through several layers of connective tissue, fat, and muscle - all with only local anesthetic - to expose a suitable vein for IV catheterization.
- f. The Lethal Injection Protocol fails to provide for the acquisition, storage and placement of any local anesthetic in the execution chamber.

- g. A cut-down is a complicated medical procedure requiring equipment and skill that has a high probability of not proceeding properly in the absence of adequately trained and experienced personnel, and without the necessary equipment.
- h. The Lethal Injection Protocol fails to provide for persons possessing training and skill required for successful cut-down and for the necessary equipment.
- i. If done improperly, the cut-down process can result in very serious complications including severe hemorrhage (bleeding), pneumothorax (collapse of a lung which may cause suffocation), and improper seating of the catheter resulting in infiltration of the pentobarbital to surrounding tissue.
- j. Cut-downs are outdated and are only used in clinical situations that are not pertinent to executions by lethal injection, including emergency scenarios where there has been extensive blood loss, and in situations involving very small pediatric patients and premature infants.
- k. Cut-downs have been replaced by the percutaneous technique which is less invasive, less painful, less mutilating, faster, safer, and less expensive than the cut-down technique.
- l. The use of a cut-down as a back-up before trying to find percutaneous access is a profound departure from standard medical methods and from the standard of care used in executions in other jurisdictions.
- m. To use a cut-down as the backup method of achieving IV access defies contemporary medical standards and would be a violation of any modern standard of decency.

- n. The Lethal Injection Protocol is silent on the procedures that will be followed by the Physician should a cut-down become necessary (Plaintiffs' Exhibit A p.67).
- o. The Lethal Injection Protocol gives the Physician complete discretion to "choose a different method to find an IV site" (Plaintiffs' Exhibit A p.67).
- p. The Lethal Injection Protocol is completely silent on permissible options for finding an IV site and obtaining venous access and whether they are medically sound, constitutional and minimize unnecessary pain.
- q. The Protocol is silent as to the Physician's qualifications and training to perform "a different method" of inserting the primary IV line.

253. There is a substantial risk that a leak in the tubing, junctions, or valves can result in the failure to properly administer a full dosage of pentobarbital to Plaintiffs.

254. The failure to administer a full dose of pentobarbital to Plaintiffs will result in an excruciatingly painful and horrifying death.

255. Problems with IV lines detaching and spilling chemicals is a known risk which has occurred in the State of Texas.

256. The Lethal Injection Protocol fails to indicate whose responsibility it is, if any, to watch the IV lines for leaks in the tubing, junctions, and valves during the administration of the pentobarbital and what member(s) of the Execution Team should do when a leak is found. *See* Plaintiffs' Exhibit A p.43.

257. The failure to designate a person to be responsible for examining and monitoring IV lines for leaks in the tubing, junctions, and valves during the administration of the pentobarbital and assure that such person has the skill and training to correct any such leaks

creates a substantial risk of error in the administration of intravenous drugs and is contrary to standard medical practices and procedures necessary to minimize this risk.

258. Should there be an error in the administration of pentobarbital during Plaintiffs' executions resulting in the administration of an inadequate amount of pentobarbital during Plaintiffs' executions, there is a substantial risk that Plaintiffs will suffer unnecessary and serious pain.

259. There is a substantial risk that the catheters used in the Lethal injection Protocol will become dislodged during the injection of pentobarbital.

260. The only monitoring of the catheters prescribed by the Lethal Injection Protocol during the administration of the Lethal Injection Chemicals is "by watching the monitor in his room which displays the exact location of the catheter(s) by means of a pan-tilt zoom camera" (Plaintiffs' Exhibit A p.43).

261. The person responsible for such monitoring is also responsible for recording time data on the Chemical Administration Record. *See* Plaintiffs' Exhibit A p.43.

262. The monitoring of an IV site from a remote camera creates a substantial risk of error in the administration of intravenous drugs and is contrary to standard medical practices and procedures necessary to minimize this risk.

263. Should there be an error in the administration of pentobarbital during Plaintiffs' executions resulting in the administration of an inadequate amount of pentobarbital during Plaintiffs' executions, there is a substantial risk that Plaintiffs will suffer unnecessary and serious pain.

264. In order to ensure that an IV does not migrate, infiltrate, move, and is working properly, the IV site must be monitored from the bedside.

265. The Lethal Injection Protocol does not provide for anyone to monitor the IV site from the bedside, nor is there any qualified medical personnel in the room to do any personal, medical monitoring of the process. *See* Plaintiffs' Exhibit A p.43.

266. The failure to provide for anyone to monitor the IV site from the bedside, or for any qualified medical personnel in the room to do any personal, medical monitoring of the process creates a substantial risk of error in the administration of pentobarbital.

267. Should there be an error in the administration of pentobarbital during Plaintiffs' executions resulting in the administration of an inadequate amount of pentobarbital during Plaintiffs' executions, there is a substantial risk that Plaintiffs will suffer unnecessary and serious pain.

268. The Lethal Injection Protocol fails to include safeguards that would protect the prisoner in the event a stay of execution is entered after the lethal injection process has begun.

- a. The Lethal Injection Protocol does not indicate what training, education, or licensing the IV Team, the Execution Team and the medical doctor has, if any, in reviving Plaintiffs in the event a stay is issued after the execution begins.
- b. The Lethal Injection Protocol does not provide for emergency life saving equipment in the execution chamber.
- c. The Lethal Injection Protocol fails to provide any protections to prevent Plaintiffs from being wrongly executed should a reprieve be granted after the process has begun but before death has occurred. *See Baze*, 553 U.S. at 46.

- c. Any resuscitation would require the close proximity of the necessary equipment, medication, and properly trained personnel.
- d. The omission of such personnel and equipment under the Lethal Injection Protocol constitutes/increases the substantial risk of serious harm to Plaintiffs and undermines the constitutionality of the procedure.

269. The failure of the Lethal Injection Protocol to provide for procedures, personnel, and training for the revival of Plaintiffs in the event it becomes necessary creates a substantial risk that Plaintiffs will not be revived, will be revived only after suffering unnecessary and serious pain, or will be revived only after suffering unnecessary, painful, and permanent bodily injury and is contrary to standard medical practices and procedures necessary to minimize this risk.

270. The Lethal Injection Protocol fails to require and include, and fails to comport with, accepted medical practices necessary to minimize the known risks involved in execution by lethal injection. The Lethal Injection Protocol increases the substantial risk that the Plaintiffs will not receive an adequate dose of pentobarbital to cause the cessation of electrical activity in the heart (*i.e.*, death) and Plaintiffs will suffer unnecessary pain.

271. Defendant Schofield (and/or one or more other Defendants) knew or should have known each fact alleged in this Count and they have acted and/or continue to act, with deliberate indifference to the same.

272. The Lethal Injection Protocol therefore violates the Eighth and Fourteenth Amendments to the United States Constitution and Tennessee Constitution Article 1, § 16.

273. By adhering to the Lethal Injection Protocol, Defendants will violate the Eighth and Fourteenth Amendments to the United States Constitution and Tennessee Constitution Article 1, § 16 and 42 U.S.C. § 1983.

COUNT VII

THE LETHAL INJECTION PROTOCOL VIOLATES FEDERAL AND STATE DRUG LAWS AND THE UNITED STATES AND TENNESSEE CONSTITUTIONS

274. Plaintiffs incorporate the preceding paragraphs in their entirety.

275. Under Tennessee's Lethal Injection Protocol, Defendants intend to procure, possess, dispense, and/or administer pentobarbital and/or compounded pentobarbital to Plaintiffs in order to kill the Plaintiffs.

276. Under Tennessee's Lethal Injection Protocol, Defendant Carpenter shall contact Defendant Physician(s) to secure a prescription for pentobarbital and/or compounded pentobarbital which Defendants intend to administer to Plaintiffs to kill Plaintiffs.

277. Defendant Pharmacist(s) will fill that prescription and deliver pentobarbital and/or compounded pentobarbital to Defendants which Defendants will then dispense and/or administer to Plaintiffs to kill Plaintiffs.

278. Under federal and Tennessee drug laws, pentobarbital is a Schedule II controlled substance.

279. Under federal and Tennessee drug laws, any compound, mixture, preparation, etc., that contains pentobarbital is a Schedule III controlled substance.

280. 21 U.S.C. §§ 822(a)(1) & (2) requires registration of every person who manufactures or distributes any controlled substance, or who proposes to engage in the

manufacture or distribution of any controlled substance, and every person who dispenses, or who proposes to dispense, any controlled substance.

281. 21 C.F.R. § 1301.11(a) requires every person who manufactures, distributes, dispenses, imports, or exports any controlled substance or who proposes to engage in the manufacture, distribution, dispensing, importation or exportation of any controlled substance shall obtain a registration.

282. Tenn. Code Ann. § 53-11-302(a) provides that every person who manufactures, distributes, or dispenses any controlled substance within this state must obtain annually a registration.

283. Tenn. Code Ann. § 53-11-302(b) provides that persons registered to manufacture, distribute or dispense controlled substances may do so only to the extent authorized by their registration.

284. It is unknown whether Defendants possess the registration and licenses required to manufacture, distribute, dispense and administer pentobarbital and/or compounded pentobarbital.

285. 21 U.S.C. § 353(b)(1)(A) provides that:

A drug intended for use by man which because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug[,] shall be dispensed only (i) upon a written prescription of a practitioner licensed by law to administer such drug, or (ii) upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist. . . .

286. 21 U.S.C. § 802(10) provides that before a controlled substance can be dispensed, there must be a lawful order, such as a prescription, from a practitioner.

287. 21 U.S.C. § 829(a) provides that unless a practitioner directly dispenses a Schedule II controlled substance, such as pentobarbital, to an ultimate user, no Schedule II controlled substance may be dispensed without a written prescription from a practitioner.

288. Tenn. Code Ann. § 53-11-303(c) provides that if practitioners are authorized to dispense under state law, they must be registered to dispense Schedule II and Schedule III controlled substances.

289. Tenn. Code Ann. § 53-11-308 provides that no Schedule II controlled substance, such as pentobarbital, may be dispensed without the written prescription of a practitioner.

290. 21 U.S.C. § 829(b) provides that unless a practitioner directly dispenses a Schedule III controlled substance, such as a substance containing pentobarbital, to an ultimate user, no Schedule III controlled substance may be dispensed without a written or oral prescription from a practitioner.

291. 21 C.F.R. § 1306.04(a) establishes that a prescription for a controlled substance is legal only when a practitioner, acting in the usual course of his or her professional practice, issues it for a legitimate medical purpose.

292. Tenn. Code Ann. § 53-11-401(a)(1) makes it unlawful for any person to distribute or dispense a controlled substance for any purposes other than those authorized by and consistent with the person's professional or occupational licensure or registration law, or to distribute or dispense any controlled substance in a manner prohibited by the person's professional or occupational licensure or registration law.

293. 21 C.F.R. § 1306.06 provides that a prescription for a controlled substance may only be filled by a pharmacist or practitioner acting in the usual course of his or her professional practice.

294. Under 21 U.S.C. § 844, it is unlawful for any person to knowingly and intentionally possess a controlled substance unless pursuant to a valid prescription or order from a practitioner acting in the course of his or her professional practice.

295. Tenn. Code Ann. §53-401(a)(2) makes it unlawful for any person who is a registrant to manufacture a controlled substance not authorized by the registrant's registration, or to distribute or dispense a controlled substance not authorized by the registrant's registration to another registrant or other authorized person.

296. Tenn. Code Ann. § 53-11-402(a)(1) makes it unlawful for any person to knowingly or intentionally distribute as a registrant a Schedule II controlled substance, such as pentobarbital, except to another registrant pursuant to an order form.

297. Tenn. Code Ann. § 53-11-402(a)(3) makes it unlawful for any person to knowingly or intentionally acquire or obtain, or attempt to acquire or attempt to obtain, possession of a controlled substance by misrepresentation, fraud, forgery, deception or subterfuge.

298. Plaintiffs have no physician-patient or pharmacy-patient relationship with any of the Defendants, including Defendant Physician(s) and Defendant Pharmacist(s), and renounce any such relationship which any Defendants in any way would intend to establish without Plaintiffs' consent.

299. Plaintiffs do not consent and do not give informed consent to any Defendants to seek, write, issue and/or fill any prescription or order for pentobarbital and/or compounded pentobarbital which Defendants would use or administer to Plaintiffs.

300. Plaintiffs do not consent to and do not give informed consent to any Defendants to administer pentobarbital and/or compounded pentobarbital to them at any time, and they do not consent or provide informed consent to any Defendants to kill him using pentobarbital and/or compounded pentobarbital.

301. Killing a human being is not a legitimate medical purpose.

302. Killing Plaintiffs who have no legitimate physician-patient relationship with Defendants also fails to establish a legitimate medical purpose for a prescription.

303. Defendant Physician(s) who issues an order or prescription that pentobarbital and/or any compound, mixture, preparation, etc., containing pentobarbital be dispensed for use in carrying out Plaintiffs' executions does not act in the usual course of the practitioner's professional practice and does not act lawfully.

304. Defendant Pharmacist(s) who fills a prescription for pentobarbital and/or any compound, mixture, preparation, etc. containing pentobarbital to be dispensed for use in Plaintiffs' executions does not act in the usual course of the practitioner's professional practice and does not act lawfully.

305. Defendant Physician(s) and Defendant Pharmacist(s) distribution or dispensation of pentobarbital and/or compounded pentobarbital for use in Plaintiffs' executions is not authorized by and consistent with the Defendants' professional or occupational licensure or registration law.

306. Defendant Physician(s) and Defendant Pharmacist(s) distribution or dispensation of pentobarbital and/or compounded pentobarbital for use in Plaintiffs' executions is prohibited by Defendants' professional or occupational licensure or registration law.

307. Defendant Physician(s) and Defendant Pharmacist(s) who either issues and orders a prescription or fills a prescription for pentobarbital and/or compounded pentobarbital for administration to Plaintiffs to kill Plaintiffs acts in violation of Tennessee law, ethics governing Tennessee physicians and pharmacists and/or their professional oaths, including, if applicable, the Hippocratic Oath.

308. Defendant Physician(s) and Defendant Pharmacist(s) who, under the Lethal Injection Protocol, train execution personnel and/or any physician or emergency medical technician involved in any part of the execution process to be used upon Plaintiffs also act in violation of Tennessee law, ethics governing Tennessee physicians and pharmacists and/or their professional oaths, including, if applicable, the Hippocratic Oath.

309. A prescription or order for pentobarbital and/or compounded pentobarbital for use in Plaintiffs' execution is not issued by Defendant Physician(s) acting in the course of his or her professional practice.

310. A prescription or order for pentobarbital and/or compounded pentobarbital for use in Plaintiffs' execution is not a valid prescription issued by Defendant Physician(s) acting in the course of his or her professional practice.

311. Under 21 U.S.C. § 841(a), unless authorized by the federal Controlled Substance Act, it is unlawful for any person to knowingly or intentionally manufacture, distribute, or dispense or possess with intent to manufacture, distribute or dispense, a controlled substance.

312. Under 21 U.S.C. § 802(15), “manufacturing” includes the production, preparation, propagation, compounding or processing of a drug or other substance, either directly or indirectly or by extraction from substances of natural origin, or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of such substance or labeling or re-labeling of its container; except that such term does not include the preparation, compounding, packaging, or labeling of a drug or other substance in conformity with applicable State or local law by a practitioner as an incident to his administration or dispensing of such drug or substance in the course of his professional practice. *See also* Tenn. Code Ann. §§ 39-17-402(15), 63-10-204(21).

313. Under 21 U.S.C. § 802(11), “distribute” means to deliver, other than by administering or dispensing, a controlled substance or listed chemical. *See also* Tenn. Code Ann. §§ 39-17-402(9), 63-10-204(13).

314. Under 21 U.S.C. § 802(10), “dispense” means to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of a practitioner including the prescribing and administering of a controlled substance and the packaging, labeling or compounding necessary to prepare the substance for delivery. *See also* Tenn. Code Ann. §§ 39-17-402(7); 63-10-204(12).

315. Under 21 U.S.C. § 802(2), “administer” refers to the direct application of a controlled substance to the body of a patient or research subject by a practitioner (or, in his presence, by his authorized agent), or the patient or research subject at the direction and in the presence of the practitioner, whether such application be by injection, inhalation, ingestion, or any other means. *See also* Tenn. Code Ann. §§ 39-17-402(1); 63-10-204(1).

316. Under 21 U.S.C. § 802(8), “deliver” or “delivery” means the actual, constructive, or attempted transfer of a controlled substance or a listed chemical, whether or not there exists an agency relationship. *See also* Tenn. Code Ann. §§ 39-17-402(6), 63-10-204(8).

317. Under 21 U.S.C. § 842, it is unlawful to distribute or dispense a controlled substance in violation of 21 U.S.C. § 829.

318. Under 21 U.S.C. § 846, it is also unlawful for any person to attempt or conspire to commit any offense contained in the federal Controlled Substances Act, 21 U.S.C. § 801 *et seq.*

319. Defendant(s)’ manufacturing, possession, delivery, distribution, dispensation, and administration of pentobarbital and/or compounded pentobarbital for Plaintiffs’ executions violates federal and state laws.

320. Under 21 U.S.C. § 321(p), a new drug includes any drug whose composition is not generally recognized among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof.

321. As to new drugs, 21 U.S.C. § 355 mandates a new drug application approved by the Secretary of Health and Human Services.

322. The pentobarbital and/or compounded pentobarbital which Defendants intend to prescribe, to manufacture, to fill a prescription of, and/or administer to Plaintiffs are new drugs for which there has been no new drug application made or approved by the Secretary of Health and Human Services.

323. The pentobarbital and/or compounded pentobarbital that Defendants intend to prescribe, to manufacture, to fill a prescription of, and/or administer to Plaintiffs are misbranded under 21 U.S.C. §§ 331 and 352.

324. Defendants' actions under the Lethal Injection Protocol, with respect to obtaining and using pentobarbital and/or compounded pentobarbital for Plaintiffs' executions, violate federal and state laws.

A.

**IN VIOLATION OF THE SUPREMACY CLAUSE OF THE UNITED STATES CONSTITUTION
(ARTICLE VI § 2), DEFENDANTS' LETHAL INJECTION PROTOCOL PROVIDING FOR THE
PROCUREMENT AND USE OF PENTOBARBITAL AND/OR COMPOUNDED PENTOBARBITAL IS
FACIALLY VOID AND UNLAWFUL**

325. Plaintiffs incorporate the preceding paragraphs in their entirety.

326. The Constitution of the United States and all federal statutes and treaties comprise the Supreme Law of the Land (U.S. Const. Art. VI § 2) and all state law or policy that conflicts with or violates the United States Constitution or federal law cannot stand.

327. Under Tennessee's Lethal Injection Protocol, it is impossible for the Defendants and the Tennessee Department of Correction to prescribe, issue a valid prescription for, procure, receive, manufacture, deliver, distribute, fill a valid prescription for, possess, dispense, and/or administer pentobarbital or any compounded pentobarbital, compound, mixture, preparation, or other substance containing pentobarbital to Plaintiffs without violating, attempting to violate, or conspiring to violate all of the federal statutes and regulations cited herein, including but not limited to 21 U.S.C. §§ 321, 331, 352, 353, 355, 802(10), 802(11), 802(15), 822, 829, 841, 844, 846, and 21 C.F.R. §§ 1301.11, 1306.04, 1306.06.

328. The Lethal Injection Protocol is therefore facially void under the Supremacy Clause of the United States Constitution, Article VI § 2.

B.

DEFENDANTS' LETHAL INJECTION PROTOCOL AND USE AND ATTEMPTED USE UPON PLAINTIFFS OF PENTOBARBITAL AND/OR COMPOUNDED PENTOBARBITAL IS UNLAWFUL AND ILLEGAL AND VIOLATES THE EIGHTH AND FOURTEENTH AMENDMENTS TO THE UNITED STATES CONSTITUTION

329. Plaintiffs incorporate the preceding paragraphs in their entirety.

330. The Eighth and Fourteenth Amendments to the United States Constitution prohibit the carrying out of an execution by a lethal injection of drugs that are unlawfully obtained or otherwise secured or possessed, used or administered in violation of the United States Constitution or the laws of the United States.

331. For all the reasons stated in this Count, Defendants do, have, will, are attempting to, have attempted to, are conspiring to, and/or have conspired to: violate federal law; unlawfully prescribe, fill a prescription for, manufacture, procure and/or receive pentobarbital, compounded pentobarbital, or any compound, mixture, preparation, or other substance containing pentobarbital; knowingly and/or intentionally manufacture and/or distribute and/or dispense pentobarbital, compounded pentobarbital, or any compound, mixture, preparation, or other substance containing pentobarbital; knowingly and intentionally possess with intent to manufacture, deliver, distribute or dispense pentobarbital, compounded pentobarbital, or any compound, mixture, preparation, or other substance containing pentobarbital, all in violation of federal law, including but not limited to 21 U.S.C. §§ 321, 331, 352, 353, 355, 802(10), 802(11), 802(15), 822, 829, 841, 844, 846, and 21 C.F.R. §§ 1301.11, 1306.04, 1306.06.

332. The pentobarbital, compounded pentobarbital, or any compound, mixture, preparation, or other substance containing pentobarbital that Defendants have or will procure, prescribe, fill a prescription for, deliver, possess, possess with intent to distribute or dispense, and/or administer or use upon Plaintiffs, is or will be unlawfully obtained, and secured and possessed in violation of federal law and the Supreme Law of the Land, and therefore, the use or administration of such pentobarbital, compounded pentobarbital, or any compound, mixture, preparation, or other substance containing pentobarbital upon Plaintiffs violates the Eighth and Fourteenth Amendments to the United States Constitution.

C.

AS APPLIED TO PLAINTIFFS, DEFENDANTS' LETHAL INJECTION PROTOCOL AND USE AND ATTEMPTED USE UPON PLAINTIFFS OF PENTOBARBITAL AND/OR COMPOUNDED PENTOBARBITAL IS UNLAWFUL AND ILLEGAL AND VIOLATES THE SUPREMACY CLAUSE OF THE UNITED STATES CONSTITUTION (ARTICLE VI § 2)

333. Plaintiffs incorporate the preceding paragraphs in their entirety.

334. The Constitution of the United States and all federal statutes and treaties comprise the Supreme Law of the Land (U.S. Const. Art. VI §2) and all state law or policy that conflicts with or violates the United States Constitution or federal law cannot stand.

335. For all the reasons stated in this Count, Defendants do, have, will, are attempting to, have attempted to, are conspiring to, and/or have conspired to: violate federal law; unlawfully prescribe, fill a prescription for, manufacture, deliver, procure and/or receive pentobarbital, compounded pentobarbital, or any compound, mixture, preparation, or other substance containing pentobarbital; knowingly and/or intentionally manufacture and/or distribute and/or dispense pentobarbital, compounded pentobarbital, or any compound, mixture, preparation, or

other substance containing pentobarbital; knowingly and intentionally possess with intent to manufacture, deliver, distribute or dispense pentobarbital, compounded pentobarbital, or any compound, mixture, preparation, or other substance containing pentobarbital, all in violation of federal law, including but not limited to 21 U.S.C. §§ 321, 331, 352, 353, 355, 802(10), 802(11), 802(15), 822, 829, 841, 844, and/or 846, and 21 C.F.R. §§ 1301.11, 1306.04 and/or 1306.06.

336. The pentobarbital, compounded pentobarbital, or any compound, mixture, preparation, or other substance containing pentobarbital that Defendants have or will procure, prescribe, manufacture, deliver, fill a prescription for, possess, possess with intent to distribute or dispense, and/or administer to or use upon Plaintiffs, is unlawfully obtained, and secured and possessed in violation of federal law and the Supreme Law of the Land, and therefore, the use or administration of such pentobarbital, compounded pentobarbital, or any compound, mixture, preparation, or other substance containing pentobarbital upon Plaintiffs violates the Supremacy Clause of the United States Constitution, Article VI § 2.

D.

FACIALLY AND AS APPLIED TO PLAINTIFFS, DEFENDANTS' LETHAL INJECTION PROTOCOL AND ITS USE AND ATTEMPTED USE UPON PLAINTIFFS IS VOID AND UNLAWFUL AND VIOLATES ARTICLE I § 8 OF THE TENNESSEE CONSTITUTION

337. Plaintiffs incorporate the preceding paragraphs in their entirety.

338. Article I, Section 8, of the Tennessee Constitution limits the authority of the state, state actors, and their employees, associates and/or contractors to deprive Plaintiffs of their lives. They can only do so through a process that comports with "the law of the land."

339. Federal law is "the law of the land."

340. State law is the "law of the land."

341. For the reasons set out in this Count, Defendants do, have, will, are attempting to, have attempted to, are conspiring to, and/or have conspired to: violate federal and state law; unlawfully prescribe and/or fill a prescription for, procure, receive, deliver, distribute and/or manufacture pentobarbital, compounded pentobarbital, or any compound, mixture, preparation, or other substance containing pentobarbital; knowingly and/or intentionally manufacture and/or distribute and/or deliver and/or dispense pentobarbital, compounded pentobarbital, or any compound, mixture, preparation, or other substance containing pentobarbital; knowingly and intentionally possess with intent to manufacture, distribute, deliver, or dispense pentobarbital, compounded pentobarbital, or any compound, mixture, preparation, or other substance containing pentobarbital, all in violation of federal law, including but not limited to 21 U.S.C. §§ 321, 331, 352, 353, 355, 802(10), 802(11), 802(15), 822, 829, 841, 844, 846, and 21 C.F.R. §§ 1301.11, 1306.04, 1306.06, and state law, including but not limited to Tenn. Code Ann. §§ 39-17-402, 403, 408, 410; §§ 53-11-301, 302, 303, 307, 308, 401, 402; §§ 63-10-204; and Tenn. Comp. R. & Regs. 1140-01-.01 through 1140-13-.08.

342. The Lethal Injection Protocol on its face and as applied to Plaintiffs, and the actions of the Defendants and the Tennessee Department of Correction in using their Lethal Injection Protocol to secure and use pentobarbital and to thereby kill Plaintiffs thus violates Article I, § 8 of the Tennessee Constitution.

E.

**FACIALLY AND AS APPLIED TO PLAINTIFFS, DEFENDANTS' LETHAL INJECTION PROTOCOL
AND ITS USE AND ATTEMPTED USE UPON PLAINTIFFS VIOLATES STATE LAW
AND ARTICLE I, §§ 8 AND 16 OF THE TENNESSEE CONSTITUTION**

343. Plaintiffs incorporate the preceding paragraphs in their entirety.

344. To the extent Tennessee's drug laws incorporate and/or rely upon federal drug laws, the actions of Defendants under the Tennessee Lethal Injection Protocol, as set forth within this Count, violate state law.

345. Defendants' manufacture, distribution, delivery, possession, dispensation and/or administration of pentobarbital and/or compounded pentobarbital to be used in Plaintiffs' executions, without the required registration and licenses and without a valid prescription written for a valid purpose, violates Tennessee's drug control laws, as well as Tennessee's pharmacy laws and regulations, including but not limited to Tennessee Code Annotated §§ 39-17-402, 403, 408, 410; §§ 53-11-301, 302, 303, 307, 308, 401, 402; §§ 63-10-204; and Tenn. Comp. R. & Regs. 1140-01-.01 through 1140-13-.08.

346. The Lethal Injection Protocol on its face and as applied to Plaintiffs, and the actions of the Defendants under the Lethal Injection Protocol to secure and use pentobarbital and/or compounded pentobarbital Plaintiffs' executions thus violates state law and Article I, §§ 8 and 16 of the Tennessee Constitution.

F.

FACIALLY AND AS APPLIED TO PLAINTIFFS, DEFENDANTS' LETHAL INJECTION PROTOCOL AND ITS USE AND ATTEMPTED USE UPON PLAINTIFFS IS VOID FOR PUBLIC POLICY

347. Plaintiffs incorporate the preceding paragraphs in their entirety.

348. Any statute, rule, regulation, or policy that requires any person or entity to violate federal or state law is void for public policy.

349. For all the reasons stated in preceding paragraphs in this Count, in order to execute Plaintiffs, Defendants do, have, will, are attempting to, have attempted to, are conspiring

to, and/or have conspired to: violate federal and state law; unlawfully prescribe, procure, fill a prescription for pentobarbital, compounded pentobarbital, or any compound, mixture, preparation, or other substance containing pentobarbital; knowingly and/or intentionally manufacture and/or distribute and/or dispense and/or administer pentobarbital, compounded pentobarbital, or any compound, mixture, preparation, or other substance containing pentobarbital; knowingly and intentionally possess with intent to manufacture, distribute dispense or administer pentobarbital, compounded pentobarbital, or any compound, mixture, preparation, or other substance containing pentobarbital, all in violation of federal and state law, including but not limited to 21 U.S.C. §§ 321, 331, 352, 353, 355, 802(10), 802(11), 802(15), 822 829, 841, 844, 846, and 21 C.F.R. §§ 1301.11, 1306.04, 1306.06; Tenn. Code Ann. §§ 39-17-402, 403, 408, 410; §§ 53-11-301, 302, 303, 307, 308, 401, 402; §§ 63-10-204; and Tenn. Comp. R. & Regs. 1140-01-.01 through 1140-13-.08.

350. The Lethal Injection Protocol on its face and as applied to Plaintiffs, and the actions of the Defendants in using their Lethal Injection Protocol to secure and use pentobarbital for Plaintiffs' executions is thus void for public policy.

G.

DEFENDANTS ARE ILLEGALLY AND UNLAWFULLY ENGAGED IN A CIVIL CONSPIRACY TO UNLAWFULLY HARM AND TO EXECUTE PLAINTIFFS

351. Plaintiffs incorporate the preceding paragraphs in their entirety.

352. A civil conspiracy involves an agreement between two or more persons to do an unlawful act or to do a lawful act in an unlawful way. It is an agreement between two or more persons to engage in concerted action for an unlawful purpose or for some lawful purpose by

unlawful means, a tortious or wrongful act by one or more of the conspirators and injury or damage to a person.

353. Through the use, application and following of Tennessee's Lethal Injection Protocol, the Defendants are, and/or have, engaged in a civil conspiracy. Given the actions of Defendants outlined in this Count and the violations of federal law resulting from those actions, Defendants are following and have an agreement to do unlawful acts or lawful acts in unlawful ways and are engaged in concerted action for an unlawful purpose and/or are acting using unlawful means. They have agreed to do and pursue a course of any number of unlawful acts or lawful acts in pursuit of an unlawful end, and have individually or collectively taken steps and actions in furtherance of, and pursuant to their agreement, all as outlined in this Count and/or set forth in the Lethal Injection Protocol, as well as actions presently unknown but ascertainable after reasonable discovery.

354. Given all such acts of Defendants outlined in this complaint, whether planned, attempted, conspired, or actually committed, Defendants are acting and have acted for an unlawful purpose or using unlawful means to pursue their purposes. Defendants are, and/or have, engaged in wrongful acts resulting, or intending to result in injury to Plaintiffs, including executing Plaintiffs' by cruel and unusual means. *Stanfill v. Hardney*, No. M2004-02768-COA-R3-CV, 2007 WL 2827498 (Tenn. Ct. App. Sept. 27, 2007).

COUNT VIII

TENNESSEE'S SECRECY STATUTE, TENNESSEE CODE ANNOTATED § 10-7-504(h)(1), VIOLATES PLAINTIFFS' FEDERAL AND STATE CONSTITUTIONAL RIGHTS AND 42 U.S.C. § 1983

355. Plaintiffs incorporate the preceding paragraphs in their entirety.

356. As of April 29, 2013, Tennessee's Public Records laws effectively shielded from disclosure the identity of persons or entities "who or that has been or may in the future be directly involved in the process of executing a sentence of death[.]" Tenn. Code Ann. § 10-7-504(h)(1).

357. On April 29, 2013, Tennessee Code Annotated § 10-7-504(h)(1) was amended to provide that:

"person or entity" includes, but is not limited to, an employee of the state who has training related to direct involvement in the process of executing a sentence of death, a contractor or employee of a contractor, a volunteer who has direct involvement in the process of executing a sentence of death, or a person or entity involved in the procurement or provision of chemicals, equipment, supplies and other items for use in carrying out a sentence of death.

358. Records made confidential by § 10-7-504(h)(1) include, but are not limited to, records related to remuneration to a person or entity in connection with such person's or entity's participation in, or preparation for, the execution of a sentence of death. Such payments shall be made in accordance with a memorandum of understanding between the commissioner of correction and the commissioner of finance and administration in a manner that will protect the public identity of the recipients; provided, that, if a contractor is employed to participate in or prepare for the execution of a sentence of death, the amount of the special payment made to such contractor pursuant to the contract shall be reported by the commissioner of correction to the comptroller of the treasury and such amount shall be a public record.

359. On September 27, 2013, Defendants instituted the new Lethal Injection Protocol. The Lethal Injection Protocol calls for two bolus injections of 2.5 grams of the barbiturate pentobarbital.

360. Plaintiff Irick is confronted with an execution date of January 15, 2014.

361. Plaintiff West is facing an imminent execution date. On October 3, 2013, the State moved the Tennessee Supreme Court to schedule such a date.

362. Plaintiff Sutton is facing an imminent execution date. On October 3, 2013, the State moved the Tennessee Supreme Court to schedule such a date.

363. Plaintiff Miller is facing an imminent execution date. On October 3, 2013, the State moved the Tennessee Supreme Court to schedule such a date.

364. Plaintiff Hutchison is facing an imminent execution date. On October 3, 2013, the State moved the Tennessee Supreme Court to schedule such a date.

365. Defendants, the Tennessee Department of Corrections ("TDOC"), its agents, and employees, have relied upon Tennessee Code Annotated § 10-7-504(h)(1) to withhold information about how it intends to carry out Plaintiffs' executions.

366. Defendants have withheld from Plaintiffs the identities of persons or entities involved in the procurement or provision of any lethal injection chemicals (pentobarbital) for use in carrying out Plaintiffs' executions.

367. Defendants have indicated that they do not have written prescriptions and/or physician orders for any lethal injection chemicals (pentobarbital) to be used during an execution, but, in any event, such documents would not be disclosed to Plaintiffs.

368. Defendants have withheld from Plaintiffs the source of the pentobarbital intended to be used for Plaintiffs' executions.

369. Defendants have withheld from Plaintiffs the identity of the chemical manufacturer of the pentobarbital intended to be used for Plaintiffs' executions.

370. Defendants have withheld from Plaintiffs the name of the pharmacy where the prescription for pentobarbital will be filled for use in Plaintiffs' executions.

371. Defendants have withheld from Plaintiffs the source of the Active Pharmaceutical Ingredient ("API") from which the injectable form of pentobarbital (intended to be used for Plaintiffs' executions) will be made.

372. Defendants have withheld from Plaintiffs the identity of the person(s) or entity/entities who will compound the injectable form of pentobarbital intended to be used for Plaintiffs' executions.

373. Defendants have withheld from Plaintiffs the location(s) where the injectable form of pentobarbital will be compounded.

A.

**TENNESSEE CODE ANNOTATED § 10-7-504(h)(1)
DENIES PLAINTIFFS ACCESS TO THE COURTS**

374. Plaintiffs incorporate the preceding paragraphs in their entirety.

375. Plaintiffs have a fundamental right of access to the courts for a redress of grievances under the First and Fourteenth Amendments and Tennessee Constitution Article I, § 17. *Bounds v. Smith*, 430 U.S. 817, 821 (1977); *Wolff v. McDonnell*, 418 U.S. 539, 579 (1974); *Barnes v. Kyle*, 306 S.W.2d 1, 4 (Tenn. 1957).

376. The right of access to the courts includes a meaningful and effective opportunity to petition the court for redress of grievances. *Bounds v. Smith*, 430 U.S. 817, 828 (1977).

377. A meaningful and effective opportunity to petition the court includes a right to discover facts and evidence relevant to the petition's allegations. It is "relatively immutable in

our jurisprudence . . . that when governmental action seriously injures an individual and the reasonableness of the action depends on fact findings, the evidence used to prove the Government's case must be disclosed to the individual so that he has an opportunity to show that it is untrue." *Greene v. McElroy*, 360 U.S. 474, 496 (1959).

378. The Eighth Amendment of the United States Constitution and Article I, § 16 of the Tennessee Constitution protect Plaintiffs from cruel and unusual punishment. Plaintiffs' lawsuit is based on this fundamental right.

379. A condemned inmate may file suit to challenge the method of his execution. *Baze v. Rees*, 553 U.S. 35 (2008); *Hill v. McDonough*, 547 U.S. 573 (2006); *West v. Schofield*, 380 S.W.3d 105 (Tenn. App. 2012); *Abdur'Rahman v. Bredesen*, 181 S.W.3d 292 (2005). Plaintiffs' lawsuit challenges Tennessee's Lethal Injection Protocol which will be used for their executions.

380. Because there is a substantial risk that the use of pentobarbital or compounded pentobarbital, as directed by the Lethal Injection Protocol, will cause Plaintiffs to suffer unnecessary pain, Plaintiffs require the information that Defendants have withheld by invoking confidentiality under Tennessee Code Annotated § 10-7-504(h)(1).

381. For example, Defendants' withholding of information has denied Plaintiffs the means to assess: (a) the quality and potency of the pentobarbital that will be used for Plaintiffs' executions; (b) the qualifications of the compounding pharmacy or its agents ("the compounder") to make the pentobarbital for Plaintiffs' executions; (c) the adequacy of the compounder's quality assurances, if any; (d) whether the compounder's facilities are equipped to make sterile products; (e) whether the compounder's facilities are indeed sterile; (f) whether the compounder's facilities are equipped to test the identity and purity of the APIs used for compounding the pentobarbital

for use in Plaintiffs' executions; (g) whether the compounder will comply with federal and state laws when producing the pentobarbital for Plaintiffs' executions; and, (h) whether Defendants are able to comply with federal and state laws regarding controlled substances.

382. Further, because Defendants have withheld information, Plaintiffs have no means to determine: (a) whether the lethal injection drug that is manufactured for his execution will or will not actually consist of pentobarbital; if so, (b) whether it will contain a dose sufficient to kill him, rather than severely injure him, (c) whether it will have the proper pH so it does not burn or decimate the veins at the injection site, and (d) whether it will not be filled with particulate or biological matter that may lead to a painful allergic reaction or reduce its effectiveness and cause permanent brain and/or other organ damage, but not death.

383. By withholding information relevant to Plaintiffs' lawsuit the Defendants have impeded Plaintiffs' ability to prosecute this lawsuit.

384. By withholding information relevant to Plaintiffs' lawsuit the Defendants have impeded Plaintiffs' ability to prosecute this lawsuit in violation of Plaintiffs' rights and 42 U.S.C. § 1983.

B.

TENNESSEE CODE ANNOTATED § 10-7-504(h)(1) DENIES PLAINTIFFS DUE PROCESS

385. Plaintiffs incorporate the preceding paragraphs in their entirety.

386. Article I, § 8, of the Tennessee Constitution, Tennessee's law of the land provision, is generally recognized as synonymous with the due process clause of the Fourteenth Amendment to the United States Constitution. *Newton v. Cox*, 878 S.W.2d 105, 110 (Tenn. 1994).

387. “The fundamental requisite of due process of law is the opportunity to be heard” when one’s rights are to be affected. *Mullane v. Central Hanover Bank*, 339 U.S. 306, 314 (1950) (quoting *Grannis v. Ordean*, 234 U.S. 385, 394 (1949)); *Lynch v. City of Jellico*, 205 S.W.3d 384, 391 (Tenn. 2006).

388. — The opportunity to be heard is worthless unless Plaintiffs are given meaningful notice of the means and manner by which Defendants intend to execute them so that objections may be presented to this Court. See *Hamdi v. Rumsfeld*, 542 U.S. 507, 533 (2004); *LaChance v. Erickson*, 522 U.S. 262, 266 (1988).

389. Defendants’ and/or TDOC’s failure to disclose relevant information about the manner and means they intend to execute Plaintiffs constitutes a denial of notice and information necessary to plead and prove the instant lawsuit, so they may fairly be heard.

390. Defendants’ use of Tennessee Code Annotated § 10-7-504(h)(1) denies Plaintiffs their rights to due process of law and violates 42 U.S.C. § 1983.

C.

TENNESSEE CODE ANNOTATED § 10-7-504(h)(1) VIOLATES THE SUPREMACY CLAUSE

391. Plaintiffs incorporate the preceding paragraphs in their entirety.

392. Article VI of the United States Constitution establishes that the Constitution is the “supreme Law of the Land.” “[C]onstitutional right[s] . . . can neither be nullified openly and directly by state legislators or state executive or judicial officers, nor nullified indirectly by them through evasive schemes . . . whether attempted ingeniously or ingenuously.” *Smith v. Texas*, 311 U.S. 128, 132 (1940).

393. The Fourteenth Amendment directs that “[n]o State shall make or enforce any law which shall abridge the privileges or immunities of citizens of the United States . . . nor deny to any person within its jurisdiction the equal protection of the laws.”

394. The Supremacy Clause will not tolerate any legislative act, including Tenn. Code Ann. § 10-7-504(h)(1), that infringes upon the protections provided by constitutional rights.

A state acts by its legislative, its executive, or its judicial authorities. It can act in no other way. The constitutional provision, therefore, must mean that no agency of the State, or of the officers or agents by whom its powers are exerted, shall deny to any person within its jurisdiction the equal protections of the laws. Whoever, by virtue of public position under a State government, . . . denies or takes away the equal protection of the laws, violates the constitutional inhibition; and as he acts in the name and for the State. . . . This must be so, or the constitutional prohibition has no meaning. Thus the prohibitions of the Fourteenth Amendment extend to all action of the State denying equal protection of the laws; whatever the agency of the State taking the action, or whatever the guise in which it is taken.

Cooper v. Aaron, 358 U.S. 1, 16-17 (1958).

395. Defendants’ use of Tennessee Code Annotated § 10-7-504(h)(1) to withhold information about the means and manner in which they intend to execute Plaintiffs has the effect of preventing Plaintiffs from determining whether their executions will comport with the Eighth Amendment’s prohibition against cruel and unusual punishment.

396. The statute, § 10-7-504(h)(1), and Defendants’ reliance upon it, have abridged Plaintiffs’ constitutional rights pursuant to the Eighth and Fourteenth Amendments to the United States Constitution, in violation of the Supremacy Clause of the United States Constitution and 42 U.S.C. § 1983.

D.

**TENNESSEE CODE ANNOTATED § 10-7-504(h)(1) VIOLATES SEPARATION OF POWERS
AS SET FORTH IN ARTICLE II, § 2 OF THE TENNESSEE CONSTITUTION**

397. Plaintiffs incorporate the preceding paragraphs in their entirety.

398. Article II, § 2 of the Tennessee Constitution recognizes the separation of powers between the executive, legislative and judicial branches of the State government.

399. The power of the Tennessee's General Assembly to legislate is "not unlimited, and any exercise of that power by the legislature must inevitably yield when it seeks to govern the practice and procedure of the courts." *State v. Mallard*, 40 S.W.3d 473, 480-81 (Tenn. 2001).

400. The courts have "affirmative obligations to assert and fully exercise their powers, to operate efficiently by modern standards, to protect their independent status, and to fend off legislative or executive attempts to encroach upon judicial [prerogatives]." *Anderson County Quarterly Court v. Judges of the 28th Judicial Circuit*, 579 S.W.2d 875, 878 (Tenn. App. 1978).

401. By preventing disclosure of information relevant to the method and manner by which the state seeks to execute Plaintiffs, Tennessee Code Annotated § 10-7-504(h)(1) prevents Plaintiffs from fully pleading or proving their case.

402. By preventing Plaintiffs from fully pleading and proving their case, Tennessee Code Annotated § 10-7-504(h)(1) prevents judicial review of the constitutionality of Tennessee's Lethal Injection Protocol.

403. By preventing judicial review of Tennessee's Lethal Injection Protocol, § 10-7-504(h)(1) violates Tennessee's separation of powers doctrine.

PRAYER FOR RELIEF

Wherefore, this Court should:

1. Declare Tennessee's Lethal Injection Protocol to be unconstitutional under Tennessee Constitution Article 1, § 16 and the Eighth and Fourteenth Amendments to the United States Constitution.
2. Declare that any attempt by Defendants to carry out Plaintiffs' executions, and/or the carrying out of such executions, using the Lethal Injection Protocol will violate 42 U.S.C. § 1983.
3. Declare that the Lethal Injection Protocol, on its face and as applied to Plaintiffs null and void and/or unconstitutional under U.S. Const. Article VI § 2, the Eighth and Fourteenth Amendments to the United States Constitution and Article I § 8 of the Tennessee Constitution.
4. Declare that the Lethal Injection Protocol causes, requires or constitutes violations of state and federal laws, including 21 U.S.C. §§ 321, 331, 352, 353, 355, 802(10), 802(11), 802(15), 822, 829, 841, 844, 846, and 21 C.F.R. §§ 1311, 1306.04, 1306.06; state laws including but not limited to, Tenn. Code Ann. §§ 39-17-402, 403, 408, 410; §§ 53-11-301, 302, 303, 307, 308, 401, 402; §§ 63-10-204; and Tenn. Comp. R. & Regs. 1140-01-.01 through 1140-13-.08.
5. Declare that the Lethal Injection Protocol is void as contrary to public policy.
6. Declare that the Lethal Injection Protocol is void as constituting an unlawful civil conspiracy.
7. Declare that Tennessee Code Annotated § 10-7-504(h)(1) violates:
 - (a) the First Amendment to the Constitution of the United States and/or Article I, § 17 of the Tennessee Constitution;

- (b) the Fourteenth Amendment to the Constitution of the United States and/or Article I, § 8 of the Tennessee Constitution;
- (c) the Supremacy Clause in Article VI of the United States Constitution; and/or,
- (d) Article II, § 2 of the Tennessee Constitution.


8. Grant any other relief as is just and appropriate under the circumstances.

Respectfully Submitted,

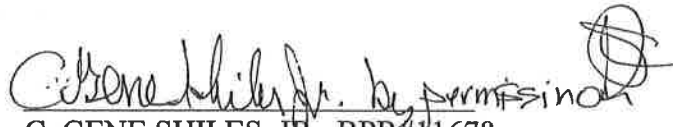
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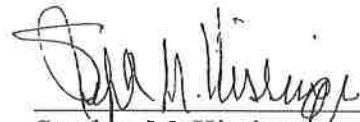
²Stephen M. Kissinger's Motion to Appear Pro Hac Vice is filed simultaneously with the instant Complaint.

CERTIFICATE OF SERVICE

I, Stephen M. Kissinger, hereby certify that a true and correct copy of the foregoing document was hand delivered to:

Mark A. Hudson
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this the 20th day of November, 2013.



Stephen M. Kissinger